The Honorable Robert S. Lasnik

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

Northwest Center for Alternatives to Pesticides, et al., Plaintiffs, v. *National Marine Fisheries Service*, Defendant.	No. 07-cv-1791-RSL **NOTICE OF WITHDRAWAL OF MOTION TO AMEND (DKT. No. 51)**

Defendant, the National Marine Fisheries Service ("NMFS"), hereby withdraws its Motion to Amend (Dkt. No. 51). On December 29, 2017, NMFS completed and transmitted to the Environmental Protection Agency ("EPA") its final Endangered Species Act biological opinion regarding EPA's registration of the pesticides chlorpyrifos, malathion, and diazinon. *See* Dkt. 69. Because Defendant's Motion to Amend sought an extension of time to finalize that biological opinion, and NMFS has now completed that same biological opinion, the Motion to Amend is moot.

Plaintiffs' Motion to Release (Dkt. No. 54) is also moot. That separate motion sought the release of certain documents because, according to Plaintiffs, they "would enable Plaintiffs to

understand whether NMFS may have any legitimate reasons for needing additional time and if so, ways to accommodate any legitimate needs while still producing the biological opinions expeditiously." *Id.* at 16. Because NMFS has completed the biological opinion at issue and is no longer requesting additional time, there is no longer any relief the Court could fashion in an order on Plaintiffs' Motion to Release. The Court should therefore dismiss the Motion to Release as moot.

Dated: December 29, 2017.

Respectfully submitted,

JEFFREY H. WOOD
Acting Assistant Attorney General
SETH M. BARSKY, Chief
S. JAY GOVINDAN, Assistant Chief

/s/ J. Brett Grosko

J. BRETT GROSKO (Maryland Bar)
Senior Trial Attorney
U.S. Department of Justice
Environment & Natural Resources Division
Wildlife & Marine Resources Section
Ben Franklin Station, P.O. Box 7369
Washington, D.C. 20044-7369
Telephone: (202) 353-0342
Facsimile: (202) 305-0275

Counsel for Defendant

Of Counsel

Daniel Pollak, Attorney-Advisor
U.S. Department of Commerce
National Oceanic and Atmospheric Administration
Office of General Counsel

CERTIFICATE OF SERVICE

I hereby certify that on December 29, 2017, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which will send notification of such to counsel of record.

/s/ J. Brett Grosko

J. Brett Grosko

Appointment

From: Gina_Shultz@fws.gov [gina_shultz@fws.gov]
Sent: 3/22/2018 11:46:58 AM
To: NMFS - HQ - PR5 Conference Line [noaa.gov_33333437383537302d343932@resource.calendar.google.com]; Miller, Wynne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8267862f7fea4782aec32ea5fec8c19c-wymiller]; Patrice Ashfield [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user1f5a6e17]; Paula.JonesYates@noaa.gov [paula.jonesyates@noaa.gov]; Perry, Tracy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ffd9b082a6484fe8a70cade93a68466c-Tracy L Perry]; cathy.tortorici@noaa.gov [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1bdaaff0c14a4264abc82f1468af694d-cathy.tortorici@noaa.gov]; craig_aubrey@fws.gov; Guilaran, Yu-Ting [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a698774e93e34a2b9181d4b3032b8a32-ytguilar]; Anderson, Brian [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce7d6e5ad2e94b3f8f5ac4d839a6c268-Brian Anderson]; sheryl.kunickis@osec.usda.gov; Sims, Diann [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7ca5706c9da345c5af43f0899cf3a8df-Diann Sims]; ashley_stilson@fws.gov; Echeverria, Marietta [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=36c56b7169144626bd6aadea25992d4e-Marietta Echeverria]

Subject: Updated invitation: ESA/Pesticide Senior Managers @ Thu Mar 22, 2018 10am - 11am (EDT) (echeverria.marietta@epa.gov)
Attachments: invite.ics
Location: NMFS - HQ - PR5 Conference Line

Start: 3/22/2018 2:00:00 PM
End: 3/22/2018 3:00:00 PM
Show Time As: Tentative

Recurrence: (none)

This event has been changed.

more details »

ESA/Pesticide Senior Managers

When **Changed:** Thu Mar 22, 2018 10am – 11am Eastern Time

Where NMFS - HQ - PR5 Conference Line (map)

Video call https://plus.google.com/hangouts/_/doi.gov/gina-shultz

Calendar echeverria.marietta@epa.gov

Who
- Gina_Shultz@fws.gov - organizer
- lois_wellman@fws.gov - creator
- miller.wynne@epa.gov
- patrice_ashfield@fws.gov
- Paula.JonesYates@noaa.gov
- perry.tracy@epa.gov
- cathy.tortorici@noaa.gov
- craig_aubrey@fws.gov
- guilaran.yu-ting@epa.gov
- anderson.brian@epa.gov

- sheryl.kunickis@osec.usda.gov
- sims.diann@epa.gov
- ashley_stilson@fws.gov
- echeverria.marietta@epa.gov

Personal Matters / Ex. 6

Agenda Items:

Status of the FWS spreadsheet
Engaging registrants in usage data catalog and collection
Public comment period on NMFS BiOp
Bomoxynil BiOp situation
The Pesticides MOA
Senate Legislation on pesticides work
CBD NOI on Malathion

Going? **Yes** - **Maybe** - **No** more options »

Appointment

From: Gina_Shultz@fws.gov [gina_shultz@fws.gov]
To: NMFS - HQ - PR5 Conference Line [noaa.gov_33333437383537302d343932@resource.calendar.google.com]; miller.wynne@epa.gov; Gina_Shultz@fws.gov [gina_shultz@fws.gov]; patrice_ashfield@fws.gov; Paula.JonesYates@noaa.gov [paula.jonesyates@noaa.gov]; perry.tracy@epa.gov; cathy.tortorici@noaa.gov; craig_aubrey@fws.gov; guilaran.yu-ting@epa.gov; anderson.brian@epa.gov; sheryl.kunickis@osec.usda.gov; sims.diann@epa.gov; ashley_stilson@fws.gov; echeverria.marietta@epa.gov

Subject: ESA/Pesticide Senior Managers
Location: NMFS - HQ - PR5 Conference Line

Start: 3/22/2018 2:00:00 PM
End: 3/22/2018 3:00:00 PM
Show Time As: Tentative

Recurrence: (none)

Participant call-in Details[Personal Matters / Ex. 6]==========
Agenda Items:

Status of the FWS spreadsheet
Engaging registrants in usage data catalog and collection
Public comment period on NMFS BiOp
Bomoxynil BiOp situation
The Pesticides MOA
Senate Legislation on pesticides work
CBD NOI on Malathion

-::~:~::~::~:~::-
Please do not edit this section of the description.

This event has a Google Hangouts video call.
Join: https://plus.google.com/hangouts/_/doi.gov/gina-shultz?hceid=Z2luYV9zaHVsdHpAZndzLmdvdg.ek2mc2dhm1npqcrcks297idlq4&hs=121

View your event at
https://www.google.com/calendar/event?action=VIEW&eid=ZWsybWMyZGhtMW5wcWNyY2tzMjk3aWRscTRfMjAxODAzMjJUMTIwMDAwWiBlY2hldmVycmlhLm1hcmlldHRhQGVwYS5nb3Y&tok=MTkjZ2luYV9zaHVsdHpAZndzLmdvdmVlNjQ3NjM3Mzg2OTdlYjc2OWQwNzMzZmI1NzgzZDZmMGY3OWZjNTc&ctz=America%2FNew_York&hl=en&es=0.
-::~:~::~::~:~::-

Message

From: Shultz, Gina [gina_shultz@fws.gov]
Sent: 9/13/2018 11:59:02 PM
To: Echeverria, Marietta [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=36c56b7169144626bd6aadea25992d4e-Marietta Echeverria]; Anderson, Brian [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce7d6e5ad2e94b3f8f5ac4d839a6c268-Brian Anderson]
CC: Craig Aubrey [craig_aubrey@fws.gov]; Patrice Ashfield [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user1f5a6e17]
Subject: Responses to EPA Comments on Draft Malathion Timeline
Attachments: Draft timeline for malathion BO for EPA 9.11.18.docx

As a reminder, I will be out of the office 9/17 - 10/5. Contact Craig or Patrice with ESA pesticide issues during that time.

Gina Shultz
Deputy Assistant Director, Ecological Services
U.S. Fish and Wildlife Service
MS: ES
5275 Leesburg Pike
Falls Church, VA 22041-3803
703-358-1985

Message

From: Shultz, Gina [gina_shultz@fws.gov]
Sent: 4/18/2018 2:23:38 PM
To: Guilaran, Yu-Ting [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a698774e93e34a2b9181d4b3032b8a32-ytguilar]
CC: lois_wellman@fws.gov; Patrice Ashfield [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user1f5a6e17]; George Noguchi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userbe760c8b]; Miller, Wynne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8267862f7fea4782aec32ea5fec8c19c-wymiller]; Echeverria, Marietta [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=36c56b7169144626bd6aadea25992d4e-Marietta Echeverria]; Perry, Tracy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ffd9b082a6484fe8a70cade93a68466c-Tracy L Perry]
Subject: Re: [EXTERNAL] Agenda? Invitation: OP Pesticide Consultation Meeting @ Thu Apr 19, 2018 3:30pm - 4:30pm (EDT) (guilaran.yu-ting@epa.gov)
Attachments: 04192018_Agenda.docx

Thank you for the reminder. I meant to send this out yesterday. Feel free to provide comments back or we can discuss tomorrow morning.

Gina Shultz
Deputy Assistant Director, Ecological Services
U.S. Fish and Wildlife Service
MS: ES
5275 Leesburg Pike
Falls Church, VA 22041-3803
703-358-1985

On Wed, Apr 18, 2018 at 9:55 AM, Guilaran, Yu-Ting <Guilaran.Yu-Ting@epa.gov> wrote:

> Hi Gina
>
> Just want to follow up from last Thur's call and see if you have an agenda for tomorrow's registrant meeting? We will see you in the falls church office hopefully a little before 3:30. Thanks.
>
> Regards,
>
> Yu-Ting Guilaran, P.E.
>
> Director
>
> Pesticide Re-evaluation Division (PRD)

Office of Pesticide Programs

Office of Chemical Safety and Pollution Prevention

(tel) 703 308 0052

(fax)703 308 8005

Mail code 7508P

Room number PY S9623

-----Original Appointment-----
From: Gina_Shultz@fws.gov [mailto:gina_shultz@fws.gov]
Sent: Monday, April 09, 2018 10:12 AM
To: paul.whatling@fmc.com; aldos.barefoot@fmc.com; rsrichardson@wileyrein.com; Patrice Ashfield; George Noguchi; mark.hough@adama.com; dweinberg@wileyrein.com; Miller, Wynne; Echeverria, Marietta; Patrick Havens; Guilaran, Yu-Ting; Nancy Golden; groliver@dow.com; laura.phelps@adama.com
Subject: Invitation: OP Pesticide Consultation Meeting @ Thu Apr 19, 2018 3:30pm - 4:30pm (EDT) (guilaran.yu-ting@epa.gov)
When: Thursday, April 19, 2018 3:30 PM-4:30 PM (UTC-05:00) Eastern Time (US & Canada).
Where: MIB - Conference Room 3038 (Personal Matters / Ex. 6)

more details »

OP Pesticide Consultation Meeting

When	Thu Apr 19, 2018 3:30pm – 4:30pm Eastern Time
Where	MIB - Conference Room 3038 (Personal Matters / Ex. 6) (map)
Video call	https://hangouts.google.com/hangouts/_/doi.gov/gina-shultz
Calendar	guilaran.yu-ting@epa.gov
Who	• Gina_Shultz@fws.gov - organizer • lois_wellman@fws.gov - creator • paul.whatling@fmc.com • aldos.barefoot@fmc.com • rsrichardson@wileyrein.com • patrice_ashfield@fws.gov • george_noguchi@fws.gov • mark.hough@adama.com • dweinberg@wileyrein.com • miller.wynne@epa.gov • echeverria.marietta@epa.gov • phavens@dow.com • guilaran.yu-ting@epa.gov

- nancy_golden@fws.gov
- groliver@dow.com
- laura.phelps@adama.com

MIB - Main Interior Building

1849 C Street, NW

Washington, DC 20240

POC - Lois Wellman at 202-208-4646

Please bring valid ID for security clearance

Going? **Yes** - **Maybe** - **No** more options »

Agenda

FWS and EPA Meeting with Representative Applicants

for Malathion, Diazinon and Chlorpyrofos

April 19, 2018

3:30 – 4:30 pm

1. Introductions
2. Brief overview of role of applicants in ESA section 7 consultations
3. Status of the ESA section 7 consultations
4. Usage data catalog

Appointment

From: cathy.tortorici@noaa.gov [cathy.tortorici@noaa.gov]
Sent: 9/12/2018 8:44:40 PM
To: Miller, Wynne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8267862f7fea4782aec32ea5fec8c19c-wymiller]; ashley_stilson@fws.gov; Paula.JonesYates@noaa.gov [paula.jonesyates@noaa.gov]; Anderson, Brian [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce7d6e5ad2e94b3f8f5ac4d839a6c268-Brian Anderson]; craig_aubrey@fws.gov; Patrice Ashfield [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user1f5a6e17]; Shultz, Gina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userd6a2f351]; Guilaran, Yu-Ting [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a698774e93e34a2b9181d4b3032b8a32-ytguilar]; Perry, Tracy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ffd9b082a6484fe8a70cade93a68466c-Tracy L Perry]; NMFS - HQ - PR5 Conference Line [noaa.gov_3333437383537302d343932@resource.calendar.google.com]; Echeverria, Marietta [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=36c56b7169144626bd6aadea25992d4e-Marietta Echeverria]; Sims, Diann [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7ca5706c9da345c5af43f0899cf3a8df-Diann Sims]; sheryl.kunickis@osec.usda.gov; lois_wellman@fws.gov

Subject: Updated invitation: ESA/Pesticide Sr. Mgrs Call @ Thu Sep 13, 2018 8am - 9am (EDT) (echeverria.marietta@epa.gov)
Attachments: invite.ics
Location: NMFS - HQ - PR5 Conference Line

Start: 9/13/2018 12:00:00 PM
End: 9/13/2018 1:00:00 PM
Show Time As: Tentative

Recurrence: (none)

This event has been changed.

more details »

ESA/Pesticide Sr. Mgrs Call

When: Thu Sep 13, 2018 8am – 9am Eastern Time - New York

Where: NMFS - HQ - PR5 Conference Line (map)

Calendar: echeverria.marietta@epa.gov

Who:
- cathy.tortorici@noaa.gov - organizer
- Paula.JonesYates@noaa.gov - creator
- miller.wynne@epa.gov
- ashley_stilson@fws.gov
- anderson.brian@epa.gov
- craig_aubrey@fws.gov
- patrice_ashfield@fws.gov
- Gina_Shultz@fws.gov
- guilaran.yu-ting@epa.gov
- perry.tracy@epa.gov
- echeverria.marietta@epa.gov
- sims.diann@epa.gov

- sheryl.kunickis@osec.usda.gov
- lois_wellman@fws.gov

Changed:
- status of useage data conversations
- status of FWS conversations with the registrants
- Any Malathion litigation news to share?
- On getting useage data for the B&P BiOp

- FWS
Participant call-in details:

Personal Matters / Ex. 6

==========
AGENDA ITEMS
-

Going? **Yes** - **Maybe** - **No** more options »

Appointment

From: cathy.tortorici@noaa.gov [cathy.tortorici@noaa.gov]
To: miller.wynne@epa.gov; ashley_stilson@fws.gov; Paula.JonesYates@noaa.gov [paula.jonesyates@noaa.gov]; anderson.brian@epa.gov; craig_aubrey@fws.gov; patrice_ashfield@fws.gov; Gina_Shultz@fws.gov [gina_shultz@fws.gov]; guilaran.yu-ting@epa.gov; perry.tracy@epa.gov; NMFS - HQ - PR5 Conference Line [noaa.gov_33333437383537302d343932@resource.calendar.google.com]; echeverria.marietta@epa.gov; sims.diann@epa.gov; sheryl.kunickis@osec.usda.gov; lois_wellman@fws.gov

Subject: ESA/Pesticide Sr. Mgrs Call
Location: NMFS - HQ - PR5 Conference Line

Start: 9/13/2018 12:00:00 PM
End: 9/13/2018 1:00:00 PM
Show Time As: Tentative

Recurrence: (none)

- status of useage data conversations
- status of FWS conversations with the registrants
- Any Malathion litigation news to share?
- On getting useage data for the B&P BiOp

- FWS
Participant call-in details:
Personal Matters / Ex. 6
==========
AGENDA ITEMS
-

-::~:~::~::~:~::-
Please do not edit this section of the description.

View your event at
https://www.google.com/calendar/event?action=VIEW&eid=M2N1cmFzOWc2ZjczMXVobGV2MjhmMm5rb2RfMjAxODA5MTNUMTI
wMDAwWiBlY2hldmVycmlhLm1hcmlldHRhQGVwYS5nb3Y&tok=MjQjY2F0aHkudG9ydG9yaWNpQG5vYWEuZ292ZDI0ZGI5ODA1Y2NkOTVl
ZmM2ZTllYjVjZTZhZjM4Y2NlM2FlZmQ1NQ&ctz=America%2FNew_York&hl=en&es=0.
-::~:~::~::~:~::-

Message

From: Cathy Tortorici - NOAA Federal [cathy.tortorici@noaa.gov]
Sent: 11/13/2017 4:54:51 PM
To: Shultz, Gina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userd6a2f351]; Craig_Aubrey@fws.gov; Patrice Ashfield [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user1f5a6e17]; Echeverria, Marietta [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=36c56b7169144626bd6aadea25992d4e-Marietta Echeverria]; Anderson, Brian [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce7d6e5ad2e94b3f8f5ac4d839a6c268-Brian Anderson]
Subject: Fwd: Pesticides litigation extension - as filed
Attachments: WILDLIFE-#301941-v1-NCAP_v__NMFS_-_stamped_Echeverria_declaration.PDF; WILDLIFE-#301940-v1-NCAP_v__NMFS_-_stamped_Rauch_Declaration.PDF; WILDLIFE-#301939-v1-NCAP_v__NMFS_-_stamped_motion_to_amend.PDF

Dear all -

I just got these today and you may already have these.

Attached are the motions to extend the pesticides deadline, and NMFS' and EPA's declarations.

Just give a call if you have questions -

Cathy T.

--
Cathy Tortorici
Chief, ESA Interagency Cooperation Division
Office of Protected Resources
NOAA's National Marine Fisheries Service
1315 East-West Highway
Silver Spring, MD 20910
(w) 301.427.8495
(c) 301.602.2193
cathy.tortorici@noaa.gov

The Honorable Robert S. Lasnik

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

Northwest Center for Alternatives to Pesticides, et al., Plaintiffs, v. *National Marine Fisheries Service*, Defendant.	NO. 07-cv-1791-RSL **MOTION TO AMEND DKT. NO. 50 (STIPULATION AND ORDER)** **NOTED ON MOTION CALENDAR: NOVEMBER 24, 2017**

Pursuant to paragraphs 5 and 9 of the parties' 2008 Stipulated Settlement Agreement (Dkt. 21), as amended on May 21, 2014 (Dkt. 50), Defendant, the National Marine Fisheries Service ("NMFS") requests that the Court amend the Court's 2014 Stipulation and Order (Dkt. 50) to provide that NMFS's nationwide Endangered Species Act ("ESA") biological opinion concerning the effects of the organophosphate ("OP") pesticides malathion, diazinon, and chlorpyrifos on all ESA-listed species under NMFS's purview be due December 31, 2019, in lieu of December 31, 2017. Dkt. 50 ¶ 2. If granted, the buffer zones governing the use of the OP pesticides will remain in place for the additional time that NMFS requests to complete the OP

biological opinion ("OP BiOp"), mitigating any harm to the ESA listed species at issue. On November 8 and 9, 2017, counsel for Defendant contacted Plaintiffs, Northwest Center for Alternatives to Pesticides, *et al.*, concerning the instant motion. On November 9, 2017, counsel for Plaintiffs stated that they received notification of the instant motion on November 8, 2017 and believe the parties have not had the opportunity to "work reasonably toward a mutually acceptable solution" pursuant to paragraph 5 of the Stipulated Settlement Agreement. Plaintiffs further stated that they will continue to confer with Defendants and will take a position when a response is due under the local rules.

I. INTRODUCTION

On August 1, 2008, the Court entered the parties' Stipulated Settlement Agreement, establishing a Consultation Schedule for NMFS to complete seven separate regional ESA biological opinions. Dkt. 21. On May 21, 2014, at the parties' request, the Court amended the parties' Stipulated Settlement to allow NMFS through December 31, 2017, to issue a final nationwide biological opinion concerning malathion, diazinon, and chlorpyrifos. Dkt. 50 ¶ 2. NMFS now requests an additional 24 months to produce a final OP BiOp for the following reasons.

First, due to the scope and complexity of the required analyses and number of public comments received, EPA was delayed in providing NMFS with the biological evaluations by 9 months. Second, additional delays have also occurred associated with the transition to the new administration and the need to brief the new agency leadership. Third, a number of technical issues have arisen in the interagency discussions on this very complex issue between FWS, EPA, and NMFS that must be addressed before NMFS finalizes its OP BiOp. Fourth, NMFS's need to coordinate with FWS as FWS prepares its counterpart nationwide OP biological opinions

concerning effects to terrestrial and freshwater species. For these reasons, and for those set forth in the accompanying declarations of Samuel D. Rauch, Deputy Assistant Administrator for Regulatory Programs for the National Marine Fisheries Service, and Marietta Echeverria, the Director of the Environmental Fate and Effects Division of the Environmental Protection Agency, the interests of justice favor amending the Stipulated Settlement. The Court should accordingly alter the May 21, 2014 Stipulation and Order (Dkt. 50) to relieve NMFS from the obligation to produce a final OP BiOp by December 31, 2017 and instead require NMFS to issue a final OP BiOp on or before December 31, 2019.

II. LEGAL BACKGROUND

A. THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT

Subject to limited exceptions, a pesticide may be distributed or sold in the United States only if it is registered by EPA under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"). 7 U.S.C. § 136a(a). Under FIFRA, EPA must register a pesticide if, among other things, the pesticide, when used in accordance with widespread and commonly recognized practice, generally will not cause "unreasonable adverse effects on the environment." 7 U.S.C. § 136a(c)(5). Once a pesticide is registered, EPA must periodically review that pesticide registration. 7 U.S.C. §§ 136a(g), 136a-1. If EPA determines at any time that a registered pesticide, including its approved labeling, no longer meets the standard for registration, EPA may initiate cancellation proceedings. In the case of an "imminent hazard," EPA may commence proceedings to suspend the registration of a pesticide during the period necessary to complete cancellation proceedings. 7 U.S.C. § 136d(b), (c).

B. THE ENDANGERED SPECIES ACT

Under Section 7(a)(2) of the ESA, each federal agency must insure that any action

authorized, funded, or carried out by the agency "is not likely to jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification" of designated critical habitat. 16 U.S.C. § 1536(a)(2). To assist federal agencies, often referred to as the "action agencies," in complying with Section 7(a)(2), the ESA and its regulations outline a process of consultation between the action agency and FWS and/or NMFS (collectively, the "Services"). Under those regulations, if an action agency determines that an action "may affect" listed species or their designated critical habitat, the action agency must pursue some form of consultation with FWS and/or NMFS. Consultation may be formal or informal. If a federal action is "likely to adversely affect" a listed species, the action agency and one or both of the Services enter into "formal consultation," a process which is described at length at 50 C.F.R. § 402.14. Agencies typically initiate "formal consultation," by preparing a biological assessment under 50 C.F.R. § 402.12(a) & (b) or a biological evaluation that comports with § 402.14. In these assessments, the action agency describes the proposed action and evaluates any effects the action may have on listed species and designated critical habitat. In "formal consultation," the Services use the action agency's assessment, along with other information, to prepare a biological opinion. In the BiOp, the Services determine whether the proposed action is likely to jeopardize the continued existence of a listed species or result in destruction or adverse modification of designated critical habitat. 16 U.S.C. § 1536(a)(2); 50 C.F.R. § 402.14. If the action is likely to jeopardize the continued existence of a listed species or adversely modify designated critical habitat, FWS and/or NMFS must provide recommended reasonable and prudent alternatives to the action, if any exist. 16 U.S.C. § 1536(b)(3)(A).

Upon receipt of a BiOp, the action agency makes the final decision about whether and in what manner to proceed in light of its ESA Section 7 obligation to insure that its action is not

likely to jeopardize any listed species or to destroy or adversely modify any designated critical habitat. 16 U.S.C. § 1536(a)(2); 50 C.F.R. § 402.15. The ESA does not, however, provide action agencies with regulatory authority to address the reasonable and prudent alternatives and associated reasonable and prudent measures to minimize take provided in a biological opinion. Rather, action agencies must utilize their existing regulatory authorities, to the extent such authorities are available, to implement any changes to their actions to address a BiOp.

III. FACTUAL BACKGROUND

Plaintiffs initiated the instant action in 2007 seeking to require NMFS to complete consultation on the effects of 37 pesticides on northwest salmonid species. Dkt. 1. In the parties' original August 1, 2008, settlement agreement, NMFS agreed to issue biological opinions on the effects of those pesticides pursuant to a Consultation Schedule. Dkt. 21.[1] On the basis of this schedule, on November 18, 2008, NMFS issued a biological opinion concerning the effects of malathion, diazinon, and chlorpyrifos on listed salmonids. Dkt. 50 at 2-6 ("2008 OP BiOp").

On April 1, 2009, Dow AgroSciences, LLC and other entities challenged the 2008 OP BiOp under the ESA, *Dow AgroSciences, LLC v. NMFS*, No. 09-cv-00824 (D. Md.) ("*Dow AgroSciences LLC*") (Dkt. No. 1). While NMFS prevailed at the district court level, *Dow AgroSciences, LLC v. NMFS*, 821 F. Supp. 2d 792 (D. Md. 2011), on appeal, the U.S. Circuit Court for the Fourth Circuit reversed, vacated, and remanded the 2008 OP BiOp to NMFS, *Dow AgroSciences, LLC v. NMFS*, 707 F.3d 462 (4th Cir. 2013).

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[1] The original Stipulated Settlement allowed for a public comment period on NMFS's draft biological opinions. Dkt. 21 ¶ 2.

Following that decision, the Court amended the Stipulated Settlement per the parties' request to allow NMFS through December 31, 2017 to complete a new OP BiOp. Dkt. 50 ¶ 2. The Court granted this amendment both to allow NMFS to complete a new OP BiOp on remand from the Fourth Circuit, and to permit NMFS to collaborate with the U.S. Department of Agriculture, EPA and FWS as recommended by the 2013 National Academy of Sciences report, "Assessing Risks to Endangered and Threatened Species from Pesticides." The parties made the amendment request pursuant to paragraph 5 of the Stipulated Settlement, which provides:

> Defendants represent that they intend to make every effort to comply with the terms of this Stipulation in good faith. If, however, through unforeseen circumstances, events should change after the Stipulation becomes effective, Defendants will notify all other parties of record as soon as reasonably possible of the change and the reason therefor. The parties agree to attempt to work reasonably toward a mutually acceptable solution. In the event a solution is reached, the parties shall jointly move this Court to amend the Stipulation, as the parties agree that this Stipulation may be amended or modified only by order of this Court.

Dkt. 21 ¶ 5. NMFS's current deadline for publishing a final replacement OP BiOp is December 31, 2017. Dkt. 50 at ¶ 2.

IV. ARGUMENT

NMFS requests that the Court enter an order providing a two-year extension to complete the new OP BiOp. Dkt. 21 ¶ 9. It is appropriate to amend the Stipulated Settlement to relieve NMFS of its December 31, 2017 deadline due to changed circumstances. *Id.* ¶¶ 5, 9. NMFS requests that the Court instead allow NMFS to finalize the OP BiOp before December 31, 2019.

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A. Significant Unforeseen Delay and Needed Interagency Coordination Has Rendered it Impossible for NMFS to Meet its December 31, 2017 Deadline for the OP BiOp.

Paragraph 9 of the Stipulated Settlement permits any party to apply for any order that may be "necessary to . . . resolve any dispute regarding the terms or conditions of the Stipulated Settlement Agreement, and for granting any further relief as the interests of justice may require." Dkt. 21 ¶ 9. Paragraph 5 explicitly contemplated the possibility that the terms of the Settlement Agreement would need to change due to unforeseen circumstances. *Id.* ¶ 5. Here the interests of justice support the requested extension.

First, EPA delivered its biological evaluations in January 2017 instead of March 2016, as it had originally anticipated. Decl. of Samuel D. Rauch (Exh. 1) ¶ 9; Decl. of Marietta Echeverria (Exh. 2) ¶¶ 6-7. This nine month delay materially impacted NMFS's ability to prepare its new OP BiOp. Rauch Decl. ¶¶ 19-24. NMFS based the Stipulated Settlement's target date of December 31, 2017 for completion of the OP BiOp on a schedule that it developed with EPA and FWS. *Id.* Under that schedule, EPA would have put draft biological evaluations out for public comment and issued final OP biological evaluations to NMFS and FWS by March 2016. Echeverria Decl. ¶ 6; Rauch Decl. ¶¶ 19-20. NMFS estimated completion of its replacement OP BiOp of December 31, 2017 on this March 2016 internal deadline. Rauch Decl. ¶ 20. Instead, EPA issued *draft* biological evaluations for public comment on March 31, 2016, and was not able to respond the many public comments received until in January 2017. Echeverria Decl. ¶ 6. EPA issued final biological evaluations, thus initiating formal consultation with the Services, only on January 17, 2017. *Id.* ¶ 7. This changed and unforeseen circumstance accounts for approximately nine months of the requested extension. *Id.* ¶ 6; Rauch Decl. ¶ 20.

This delay was compounded by the change in administration in January 2017. NMFS was further delayed by the unforeseen additional amount of time for EPA and the Services to appoint new agency leadership and have them confirmed by the Senate. Rauch Decl. ¶ 29. Once the new agency leadership began to arrive, EPA and the Services then needed to brief the new leadership on the very complex analyses and processes associated with the OP BiOp, which took additional time. *Id.* Because this inter-agency consultation process is uniquely and unprecedentedly collaborative and coordinated amongst the three agencies, the changes in leadership at one agency detrimentally affected the schedules of other agencies. *Id.* As a result, changes in leadership at EPA, FWS and in the Department of the Interior more broadly have also affected NMFS's ability to meet its deadline. *Id.* NMFS is striving to coordinate and remain in step with FWS and EPA. *Id.*

In addition to these factors, the OP BiOp–which is the first nationwide biological opinion ever drafted–has proven more complex than NMFS or EPA anticipated. Echeverria Decl. ¶¶ 4, 6, 11. For example, EPA's consultation obligations under the ESA involve extremely complex scientific assessments because rather than addressing effects of a discrete project at a specific location, EPA's pesticide registration actions effectively address the entire United States and therefore involve the potential for effects to hundreds of listed species in numerous and varying aquatic and terrestrial habitats. *Id.* ¶ 3; Rauch Decl. ¶¶ 6-7. The ESA risk assessment for pesticide registration must determine how each chemical enters and is dispersed in a wide variety of ecological settings, under a wide variety of usage scenarios involving different cropping and agricultural systems, and in widely varying environments. Rauch Decl. ¶ 7. It must consider how exposure to these chemicals affects a wide variety of biologically different kinds of non-target organisms, from micro-invertebrates to whales. *Id.* It must also consider how the direct

and indirect effects on individual organisms affect populations and the species as a whole. *Id.* The availability of data to inform this process varies considerably across locales, chemicals, and species. All of these complexities result in many levels of scientific uncertainty. *Id.*

Between January 2017, when EPA issued its chlorpyrifos, diazinon and malathion biological evaluations, and the present, significant issues and concerns about the methodology that EPA employed in those biological evaluations have come up. Rauch Decl. ¶¶ 3, 26. Those issues and concerns require further analysis and discussion by NMFS, EPA, and FWS and need to be resolved before NMFS issues its OP BiOp. *Id.* ¶¶ 3, 26, 31. EPA and the Services require more time to ensure that this unprecedented and novel collaborative National Academy of Sciences-recommended process continues to move forward based on shared methodologies and basis of information with appropriate input from the public. *Id.*

NMFS also needs to coordinate the release of its replacement OP BiOp with FWS. The NAS Report concluded that "What is needed is a common, scientifically credible Approach that is acceptable to EPA and the Services." *Id.* ¶ 10. It recommended a joint, nationwide approach, discussed the handling of models, data, and uncertainties associated with exposure analysis, considered various issues such as sublethal, indirect, and cumulative effects; modeling population-level effects; the effects of chemical mixtures; and incorporating uncertainties into the effects analysis. *Id.* The NAS recommended that the agencies work in a closely coordinated, collaborative fashion in order to develop and implement "a single, unified approach for evaluating risks to listed species posed by pesticide exposure under FIFRA and the ESA." *Id.* ¶ 11. FWS is currently working on its own OP biological opinions pursuant to a settlement in a separate matter, *Center for Biological Diversity v. FWS*, No. 15-568 (N.D. Cal.) (ESA suit concerning pesticide use and the California red-legged frog). Echeverria Decl. ¶ 4. EPA and the

Services have always understood that under the coordinated agency process now in place, the Services will issue their biological opinions at the same time, informed by the same inter-agency and public processes. Rauch Decl. ¶ 30. The Court should permit NMFS to collaborate with FWS to ensure the federal government is working in lockstep as it develops these first ever nationwide BiOps, as contemplated by the National Academy of Sciences. *Id.*

Finally, additional time is necessary to ensure public participation in this first-time use of a nationwide approach that will have far-reaching consequences. While the ESA and the Services' consultation regulations do not require the Services to issue draft biological opinions for public comment, given the broad extent of public interest in the evaluation and licensing of pesticides for use across the country, Congress, EPA and the Services have all agreed that meaningful public participation is a critical part of the consultation process on pesticide actions under FIFRA. Echeverria Decl. ¶¶ 8-11. During the past month, staff from EPA, FWS, and NMFS have also been discussing timelines for providing sufficient time for NMFS and FWS to complete the desired public and stakeholder processes that would follow issuance to the public of draft biological opinions. Rauch Decl. ¶ 32. Based on these discussions, the agencies anticipate that the public and stakeholder process would take an additional 18 months after the issuance by NMFS of its draft biological opinion. *Id.*

B. Buffer Zones Governing the Use of the OP Pesticides Will Remain in Place During the Pendency of the Extension.

Additionally, the buffer zones governing the use of the OP pesticides in the northwest will remain in place during the additional time requested to complete the OP BiOp. In 2010, the Plaintiffs brought a separate case in this Court under the ESA concerning EPA's OP pesticide registrations, *Northwest Center for Alternatives to Pesticides v. EPA*, No. 10-1919 (W.D.

Wash.). As part of the settlement agreement in that case, Plaintiffs negotiated protective buffer zones that apply to the use malathion, diazinon, and chlorpyrifos. *Id.* (Dkt. 124 ¶ 1). Pursuant to that agreement, users may not apply these OP pesticides within 20 yards of any salmon-supporting streams for ground applications or 100 yards of such streams for aerial applications. *Id.* (referring to Exh. 1 (*Washington Toxics Coalition v. EPA*, No. 01-132 (W.D. Wash.)), section III, paragraph A.1 to Dkt. 124)). Those buffers will remain in place until NMFS issues a new OP BiOp, thereby mitigating any harm Plaintiffs may allege will occur while NMFS completes its nationwide OP BiOp. *Id.* ¶ 2.

CONCLUSION

For the foregoing reasons, the Defendant respectfully requests that the Court alter the Court's May 21, 2014 Stipulation and Order to Amend the Stipulated Settlement Agreement Affirmed by this Court on August 1, 2008 (Dkt. 50) to allow NMFS through December 31, 2019 to issue its final OP BiOp.

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Dated: November 9, 2017.

Respectfully submitted,

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SETH M. BARSKY, Chief
S. JAY GOVINDAN, Assistant Chief

/s/ J. Brett Grosko

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CERTIFICATE OF SERVICE

I hereby certify that on November 9, 2017, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system which will send notification of such to counsel of record.

/s/ J. Brett Grosko

J. Brett Grosko

The Honorable Robert S. Lasnik

UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF WASHINGTON

NORTHWEST CENTER FOR ALTERNATIVES TO PESTICIDES, *et al.* *Plaintiffs*, v. NATIONAL MARINE FISHERIES SERVICE, *Federal Defendant.*	CASE NO. 07-1791-RSL **DECLARATION OF SAMUEL D. RAUCH IN SUPPORT OF MOTION TO AMEND DKT. 50**

1. I am the Deputy Assistant Administrator for Regulatory Programs for the National Marine Fisheries Service (NMFS). In that capacity, I oversee NMFS's fisheries regulatory actions and programs, including those to support the conservation and recovery of threatened and endangered species under the Endangered Species Act (ESA). The purpose of this affidavit is to explain the background and reasons that NMFS is now requesting alteration of the settlement agreement approved by this Court on May 21, 2014 (Settlement Agreement). Specifically, NMFS is requesting alteration of the Settlement Agreement's December 31, 2017 deadline to produce a new organophosphates biological opinion for the three pesticides,

malathion, diazinon, and chlorpyrifos. NMFS requests that the Court set a deadline of December 31, 2019 for issuance of the final NMFS biological opinion. This affidavit explains the background of and reasons for this request.

2. As described further below, the preparation of the NMFS organophosphates biological opinion is part of an unprecedented inter-agency pilot effort in which NMFS, the U.S. Fish and Wildlife Service (FWS), and the Environmental Protection Agency (EPA) (the agencies) are developing a collaborative approach to resolving the complex challenges of conducting nationwide ecological risk assessments of pesticide registration that will meet the requirements of the ESA and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The agencies are developing a pilot consultation process that, in contrast to prior such consultations, would address the effects of pesticide registration on a nationwide basis, for all listed species, rather than on a species-by-species basis. This is an approach recommended by the National Academies of Science (NAS) that is intended to be more transparent, scientifically robust, and efficient than prior such consultations.

3. The agencies have already achieved a great deal of progress in these consultations. However, as further explained below, there are several reasons these schedule alterations are needed. Due to the sheer scope and complexity of technical issues that have arisen, the agencies need more time to assure that the process continues to move forward based on shared and collaborative methodologies and a shared basis of data and information. This process has always been conceived as an iterative, collaborative process between the agencies, with extensive input from stakeholders and the public. After an extensive public and stakeholder comment process in 2016, the EPA biological evaluations that initiated the consultation process were delayed by nine months. The inter-agency process and stakeholder input have also

identified a variety of technical and methodological issues that will require lengthier and more intensive inter-agency collaborative work to address, and that will require a more extensive process than originally anticipated. In addition, NMFS has learned that certain issues and concerns will need to be discussed concerning the basis for EPA's biological evaluations, and those evaluations are in turn one of the key foundations upon which NMFS must base any final biological opinion.

4. NMFS and FWS (the Services) are responsible for protecting species that are listed as endangered or threatened under the ESA and for protecting designated critical habitats needed for such species' survival and recovery. EPA is responsible for registering and re-evaluating pesticides under FIFRA and must ensure that pesticide use does not cause any unreasonable adverse effects on the environment. Under ESA Section 7, EPA must consult with the Services to ensure that the registration of each pesticide registration does not jeopardize any listed species or destroy or adversely modify its critical habitat.

5. For decades, there has been intensive and repeated litigation over how EPA and the Services carry out their compliance with the ESA on the EPA's pesticide registration program. Litigation continues in other courts to this day. Such litigation has included cases challenging alleged delay by in completing ESA consultations; cases challenging the results of such consultations (i.e. the Services' biological opinions); and cases alleging failures by EPA in the implementation of the Services' biological opinions. The volume of litigation, and the volume and complexity of the consultations required, has in the past threatened to create intractable gridlock.

6. The current ESA consultation process on these organophosphates represents an unprecedented and ambitious pilot effort to put ESA compliance for pesticide registrations on a

new footing. The goals of this new approach are to reduce litigation, enhance the scientific rigor of the process, increase its openness and transparency, and to allow such consultations to proceed more efficiently than has been the case for prior species-by-species consultations. It is informed by an April 30, 2013 study from the NAS entitled "Assessing Risks to Endangered and Threatened Species from Pesticides" (NAS Report). The NAS Report was prepared at the request of FWS and NMFS (collectively, the Services), EPA, and the U.S. Department of Agriculture (USDA) (collectively, the agencies).

7. ESA consultation for FIFRA pesticide registrations pose formidable scientific, logistical and methodological challenges. While pesticides are registered on a nationwide basis, ESA Section 7 requires the Services to assess risk to each individual species. Under ESA Section 7, a typical consultation focuses on a single, discrete agency action occurring at a particular time and place, and its effects on one or a few species. In contrast, EPA's pesticide registration program governs the use of over a thousand different chemicals applied throughout the United States by thousands of individual users. The ESA risk assessment for pesticide registration must determine how each chemical enters and is dispersed in a wide variety of ecological settings; under a wide variety of usage scenarios involving different cropping and agricultural systems; in widely varying environments (hydrology, climate, etc.). The assessment must consider how exposure to these chemicals affects a wide variety of biologically different kinds of non-target organisms, from micro-invertebrates to whales; it must consider how the direct and indirect effects on individual organisms affect populations and the species as a whole. The availability of data (*e.g.*, on pesticide usage, toxicity; species biology, life histories, and population dynamics) varies considerably across locales, chemicals, and species. All of these complexities give rise to many levels of scientific uncertainty.

8. There are also important differences between the analytical methods and requirements that have been developed in the past by EPA to comply with FIFRA, versus the methods used by the Services under the ESA. For example, FIFRA requires the weighing the risks posed by a pesticide with the benefits of pesticide use and use, while the ESA focuses solely on species conservation. As a result, as noted by the NAS Report, the differences between the statutes "led to conflicting approaches in evaluating risks," and made it difficult to reach a "consensus on assessing risks to listed species from pesticides." NAS Report at 3. This was due in large part to the agencies' use of "different assumptions, technical approaches (data and models used), and risk-calculation methods." NAS Report at 4.

9. The agencies requested that NAS evaluate methods for identifying the best scientific data available; evaluate approaches for developing modeling assumptions; to identify authoritative geospatial information that might be used in risk assessments; to review approaches for characterizing sublethal, indirect, and cumulative effects; to assess the scientific information available for estimating effects of mixtures and inert ingredients; and to consider the use of uncertainty factors to account for gaps in data.

10. The NAS Report concluded that "What is needed is a common, scientifically credible Approach that is acceptable to EPA and the Services." NAS Report at 4. It recommended a joint, nationwide approach, discussed the handling of models, data, and uncertainties associated with exposure analysis, considered various issues such as sublethal, indirect, and cumulative effects; modeling population-level effects; the effects of chemical mixtures; and incorporating uncertainties into the effects analysis.

11. The NAS recommended that the agencies work in a closely coordinated, collaborative fashion in order to develop and implement "a single, unified approach for

evaluating risks to listed species posed by pesticide exposure under FIFRA and the ESA." NAS Report at 33. The agencies would need to work in tandem during a three-step process. In the first step, EPA determines whether a pesticide "may affect" any listed species; in the second step, EPA determines whether it is "likely to adversely affect" a listed species, and in Step 3, the Services determine whether the chemical is likely to jeopardize listed species. Crucially, NAS found that "[i]f the Services can build on the EPA assessment conducted for Steps 1 and 2 rather than conducting a completely new analysis for Step 3, the [risk analysis] will likely be more effective and scientifically credible." NAS Report at 4. Thus, the NAS concluded that implementation of the recommended approach would require close "communication and coordination throughout the process" to "understand and reconcile the differences between how EPA assesses risk to listed species from pesticide use and how the Services reach jeopardy decisions." NAS Report at 22. Such coordination would allow at every step for "EPA's expertise in pesticides to be effectively combined with the Services' expertise in life histories of listed species and in abiotic and biotic stressors of the species." NAS Report at 27.

12. In order to implement the recommendations of the NAS Report, the agencies have engaged in extensive discussions and workshops aimed at developing shared methodologies. This process included five inter-agency workshops (in August 2013, May 2014, November 2014, January 2016, and September 2016) to address the NAS recommendations and develop the technical analyses for the EPA Biological Evaluations. The agencies also hosted a stakeholder workshop on June 29-30 with representatives of affected industry and grower groups, consultants, conservation and other non-governmental organizations, the Agencies and USDA. More information on the scientific, technical, and consultation process issues that the agencies have been addressing is available in the agencies' joint *Final Report to Congress: Endangered*

Species Act Implementation in Pesticide Evaluation Programs, December 2016 (2016 Report to Congress).

13. The Agencies worked to align existing settlements and lawsuits so that they could focus on national-level consultations for all ESA-listed species, rather than focus on single species, or a small subset of species in smaller geographical areas that were the initial focus of the ESA-related litigation. Based on recent settlement agreements as part of ongoing litigation against EPA, NMFS, and USFWS, the Agencies agreed to coordinate completion of nationwide consultations for nine pesticides: carbaryl, chlorpyrifos, diazinon, malathion, methomyl, glyphosate, atrazine, propazine and simazine. The dates provided for completion of consultation in those settlements are December 2017 for chlorpyrifos, diazinon, and malathion, December, 2018 for carbaryl and methomyl, and December 2022 for glyphosate, atrazine, simazine and propazine.

14. In 2013, the agencies issued an "Interim Approaches" proposal, under which an assessment and consultation methodology would be applied to a set of pilot nationwide consultations. This proposal was termed "interim" because it would be tested on a selected group of chemicals as a pilot, and from that experience, the agencies would gain experience and information that would allow them to revisit and refine the methods as they went forward to perform consultations on other chemicals. *See* "Interim Approaches for National-Level Pesticide Endangered Species Act Assessments Based on the Recommendations of the National Academy of Sciences April 2013 Report," *available at* https://www.epa.gov/endangered-species/interim-approaches-pesticide-endangered-species-act-assessments-based-nas-report.

15. The overarching goal of the Interim Approach was to "collaboratively develop a streamlined consultation process that meets the needs of the FIFRA/ESA workload and

integrates seamlessly [EPA's Steps 1 and 2] into [the Services] Step 3." Interim Approach at 9. The Interim Approach would be "based on shared assumptions, data, analytical processes and models, [and] will be applied collaboratively as part of EPA's Registration Review program beginning in 2014." Interim Approaches at 1. The agencies would "[d]evelop a common approach to weight of evidence analyses, using qualitative information for making the NLAA/LAA (and jeopardy) decisions." Interim Approaches at 10.

16. The ESA and its regulations do not require any public comment process in the development of biological opinions. However, the agencies recognized that the pilot consultation process should not only be collaborative and coordinated, but should also strive for transparency and make extensive use of information provided by stakeholders, the public, applicants, and other affected parties. On March 19, 2013, the agencies issued a joint document entitled "Enhancing Stakeholder Input to the Pesticide Registration Review and ESA Consultation Processes and Development of Economically and Technologically Feasible Reasonable and Prudent Alternatives" (EPA Docket ID Number EPA-HQ-OPP-2012-0442) (Stakeholder Proposal). The Stakeholder Proposal noted that "Because stakeholders, including state governments, universities, and growers/users, have significant amounts of relevant information and are the ultimate implementers of pesticide labels in the field, it is critical that they have a seat at the table during the development of any needed risk reduction measures to ensure that such measures are technologically and economically feasible." Stakeholder Proposal at 2. The Stakeholder Proposal outlined the following process for receiving comment on the draft biological opinions:

> Prior to formally transmitting the draft biological opinion to EPA, the Service would provide EPA and the applicant with an opportunity to identify any perceived errors in the description of the proposed action and the effects analysis (e.g., use rates, registered uses, scope of the proposed action). Subsequent to any

> errors being corrected, the Service will provide EPA with the draft biological opinion for the purpose of analyzing the reasonable and prudent alternatives. EPA will make this draft Biological Opinion available for public comment. All comments will be submitted to EPA, although the applicant may send a copy of its comments directly to the Service. EPA will organize all of the public comments to aid the Service in their review of the comments and will highlight comments of particular note. EPA will provide the Services with all of the comments that are submitted in response to the draft Biological Opinion.
>
> It is anticipated that comments would focus on the analyses leading to the conclusions in the opinion, the conclusions themselves, and the reasonableness and practicality of any Reasonable and Prudent Alternatives in the draft biological opinion. This would provide another opportunity for the public to provide invaluable input on the RPAs as well as to provide/suggest/propose alternate risk reduction measures that accomplish the same protection goals that are easier/less costly for the grower/user community to implement.
>
> During this public comment period, EPA and the Services would specifically reach out to growers to engage in what technologically and economically feasible approaches could be implemented that minimize the impact on growers and allow them to meet their pest control needs while achieving the necessary protection goals to avoid jeopardy to threatened and/or endangered species. In particular, this process should offer affected stakeholders an opportunity to provide real world data and to identify practical considerations that affect the viability of different options for mitigating risks to species. EPA will provide a key role by focusing affected entities on the availability of the draft document and timeframes for submission of input.
>
> Upon receipt of the organized public comments from EPA, the Services will prepare a document and include it in the administration record of the consultation that details how such comments were considered and, if appropriate, how the final document was modified to address the comments. The public comments could be on the draft Biological Opinion, Reasonable and Prudent Alternatives, or Incidental Take Statement (including any comments or concerns raised by EPA that were not identified by the public). The Services will include this document in its administrative record and will provide it to EPA. Both the Services and EPA will make the document available to the public upon request.

17. As reflected in the Settlement Agreement, the agencies agreed that the first ESA consultations to implement the NAS recommendations, the Interim Approaches, and the Stakeholder Proposal, would be on the three organophosphates. The Settlement Agreement noted that "the OP biological opinion that NMFS will develop on remand should be based on new

biological evaluations that incorporate the recommendations of the NAS Report and should address impacts to all of the ESA-listed species under NMFS's jurisdiction." Settlement Agreement at 5. The agencies would "be working together on developing and testing new methodologies and a common approach." Settlement Agreement at 5. It noted that "these biological evaluations will be the first ever to address all NMFS species, and for some of NMFS's species there is far less data, information and research available than there is for salmonids." Settlement Agreement at 5.

18. Under ESA Section 7, the process of formal consultation begins when the action agency provides FWS and/or NMFS (the Services) with its evaluation of the effects of its action on ESA-listed threatened and endangered species and their designated critical habitats. For those species and habitats for which EPA concludes its action may affect, but is not likely to adversely affect, NMFS will then consider whether it can concur in that determination, which ends the consultation process for those species or habitats. For those species or habitats where EPA concludes its action is likely to adversely affect, NMFS must then prepare a biological opinion.

19. The target date in the Settlement Agreement of December 31, 2017 for completion of the organophosphates biological opinions was based on a schedule developed by the agencies under which EPA would publish draft biological evaluations out for public comment, and subsequently issue final biological evaluations to NMFS and FWS on the organophosphates by March 2016. It was on this basis that NMFS estimated completion of its biological opinion on the organophosphates by December 31, 2017, the date contained in the Settlement Agreement.

20. EPA issued draft biological evaluations for public comment on March 31, 2016, and issued a response to public comments in January 2017. *See* EPA, Response to Comments on

the Draft Biological Evaluations for Chlorpyrifos, Diazinon, and Malathion, Jan. 17, 2016, *available at* https://www3.epa.gov/pesticides/nas/final/response-to-comments.pdf (EPA Comments Response).

21. In June 2016, EPA and the Services held a two-day meeting that provided a forum for stakeholder suggestions for refining the interim methods used in the draft biological evaluations.

22. EPA received 78,000 comments on the draft biological evaluations, and identified 120 substantive comments meriting detailed review. EPA Comments Response at 2. EPA noted that "[t]he Agencies intend to refine the interim methods used in the first three pilot BEs based on a phased and iterative approach," and identified revised modeling approaches and other changes reflected in the final biological evaluations. EPA Comments Response at 2. EPA noted a number of significant issues and recommendations that had been raised that could not be fully addressed in the final biological evaluations. EPA indicated that these issues would "require further development in collaboration with the Services." EPA Comments Response at 2. These included recommendations for:

> [A] substantial reduction in the size and complexity of the assessments; a move toward more probabilistic approaches; refinements in geospatial data used to define species ranges and potential use sites; the utilization of watershed-level aquatic exposure models; improved methods for estimating exposures in riverine and estuarine/marine habitats; improved characterization and consideration of magnitude of effects; and a consideration in the timing and duration of potential pesticide exposures (e.g., linking exposure with life-history variables). Additionally, we are exploring ways to use species-specific toxicity data earlier in the first step of the [biological evaluation] process to refine, but still maintain, a protective screening process. We aim to streamline the process to a point where it is protective of species, timely for FIFRA registration review decisions, feasible within the agencies' resource constraints, and transparent to the public.

EPA Comments Response at 2.

23. The process of drafting the biological evaluations, completing a public comment process on them, and the inter-agency process where NMFS and EPA considered the public comments, has taken longer than anticipated. This was due in part to the volume of comments received, the number and complexity of the scientific and methodological issues presented, and different viewpoints among the agencies as to how to address them. Under the Interim Approaches, EPA and the Services have engaged in a significant degree of interchange and collaboration to refine the biological evaluations. The agencies have also gone to great lengths to obtain and respond to input from stakeholders as the methods are developed.

24. EPA issued final biological evaluations, thus initiating formal consultation with the Services, on January 17, 2017. This was nine months later than anticipated in the schedule that formed the basis for the Settlement Agreement's December 31, 2017 biological opinion deadline.

25. EPA's biological evaluations concluded that, with respect to species and critical habitats under NMFS's jurisdiction, its registration of the three organophosphates would adversely affect 77 listed species and 47 designated critical habitats. This includes species from a variety of regions of the United States, including turtles, salmonids, plants, sturgeon, marine fish, coral, and marine mammals. EPA also requested NMFS's concurrence with the conclusion in its biological evaluations that its action was not likely adversely affect an additional 19 listed species and three designated critical habitats under NMFS jurisdiction. EPA also initiated formal consultation at this time with FWS.

26. In April-May 2017, NMFS provided EPA with preliminary drafts of portions of its analysis for its biological opinion. On June16, 2017, EPA provided extensive comments in response, raising numerous issues and questions about NMFS's methodologies, data, and

assumptions. The comments exceeded NMFS's expectations as to the number and complexity of the issues that the agencies would need to address in working toward a coordinated, collaborative approach to the consultations.

27. As noted already, the scope and complexity of these nationwide pesticide consultations raises numerous challenges. The agencies noted in their December 2016 Report to Congress that "the interim scientific methods used to develop the Biological Evaluations including the involvement and integration of stakeholder concerns have strained existing resources of the Agencies." 2016 Report to Congress at 13-14. That Report noted that "[t]he Agencies have a finite number of staff to conduct this work and at the same time meet litigation mandated deadlines based on existing ESA-related settlement agreements." *Id.* Additionally, it noted that EPA has been sued for failure to meet its ESA obligations on new chemical registrations, potentially resulting in further resource constraints. *Id.*

28. Significant progress has been made on addressing many challenging issues. Among the accomplishments to date:

- Agency agreement on geospatial data to define pesticide use areas for agricultural and non-agricultural use patterns.
- Guidance on the construction and use of species sensitivity distributions to derive acute toxicity thresholds.
- Discussing methods for qualitative analysis of mixtures, inert ingredients, and surfactants.
- Agency agreement on aquatic habitat categories ("bins") for predicting regionally-specific aquatic exposure concentrations for each bin based on existing EPA

models, and assignment of all aquatic ESA-listed species including different life stages (e.g., juvenile vs. adult) to the appropriate bins.

- Agency agreement on the review of all registrant-submitted and open literature data for the three pilot chemicals (chlorpyrifos, malathion, and diazinon) including associated thresholds for each line of evidence and taxonomic group and associated data arrays for the three pilot chemicals.
- Agency compilation and agreement on life history data (e.g., diet, body weight, habitat, etc.) for all ESA-listed species including identification of model input parameters based on this information.
- Development of tools to advance and automate the estimation of pesticide exposures and effects for ESA-listed species for EPA's nationwide assessments.

Report to Congress at 22-23.

29. The process of issuing the NMFS draft biological opinion for public comment has also been delayed due to the change in administration in January 2017, and the time necessary for new agency leadership to be appointed by the administration and confirmed by the Senate. There has been an accompanying need to brief new leadership on these very complex analyses and processes. In addition, because this inter-agency consultation process is uniquely and unprecedentedly collaborative and coordinated, the changes in leadership at one agency affect the schedules of other agencies. So as a result, changes in leadership at EPA, FWS and the Department of the Interior have also affected NMFS's timeline because NMFS is not acting alone or unilaterally, but continually striving to coordinate and remain in step with the other agencies.

30. In recent discussions with NMFS, FWS has indicated that they will need additional time beyond December 31 to complete its biological opinions, due in large part to the need to complete a robust public process as called for in the Stakeholder Proposal. Moreover, the agencies agree that the joint public process called for in the Stakeholder Proposal will likely take longer than originally anticipated. It has always been agreed that under this coordinated agency process, FWS and NMFS would issue their biological opinions at the same time, informed by the same inter-agency and public processes.

31. During the course of the inter-agency process, the other agencies indicated to NMFS an interest in reassessing methodologies and evaluating new methodologies. As a result, the requested alterations to the schedule in the Settlement Agreement include a period of time for the agencies to consider these issues.

32. During the past month, staff from EPA, FWS, and NMFS have also been discussing timelines for providing sufficient time for NMFS and FWS to complete the desired public and stakeholder processes that would follow issuance to the public of draft biological opinions. Based on these discussions, the agencies anticipate that the public and stakeholder process would take an additional 18 months after the issuance by the Services of draft biological opinions. This 18-month period would include an opportunity for inter-agency discussions to clarify the draft biological opinion, and then a stakeholder and public input process. In the latter process, EPA would post draft biological opinions on EPA's public docket for public comment; organizing the comments, identifying key comments; and submit the comments to the Services. The Services would prepare a document responding to the comments; and the Services would then finalize the biological opinions, taking into account the information gained from these steps as appropriate. As part of the public process, EPA and the Services would seek input from

growers and other stakeholders regarding technologically and economically feasible approaches that can be implemented that minimize the impact on growers and allow them to meet their pest control needs while achieving the necessary protection goals to avoid jeopardy to threatened and/or endangered species.

33. The schedule for the process described above is somewhat longer than was originally anticipated when developing the schedules that formed the basis for the December 31, 2017 deadline reflected in the Settlement Agreement. For example, the number of issues raised by EPA regarding the preliminary draft sections of portions of the NMFS biological opinion analysis that EPA raised in June 2017 exceeded NMFS's expectations. Moreover, FWS has indicated it will require more public and stakeholder input than originally expected, and expects to work further with EPA on refining some of the data on which the risk assessments are based. The volume and substantiality of the comments received in the public comment process on EPA's biological evaluations was also greater than anticipated, and raised issues that the agencies hope to further address with the benefit of this public and stakeholder input.

34. We anticipate that FWS would follow a similar schedule to that proposed herein by NMFS, as the agencies intend to continue to move forward with a collaborative, coordinated process, as recommended by the NAS, and as further spelled out in the Interim Approaches and the Stakeholder Proposal.

35. For the above reasons, NMFS is proposing the following schedule. First, NMFS will issue to EPA a draft organophosphates biological opinion within six months from the issuance of the Court's order on this motion. During that time, the agencies would as necessary have the opportunity to continue to discuss and resolve issues raised by the other agencies regarding the methodologies underlying the consultation. Upon EPA's receipt of the draft

biological opinion, the agencies may have discussions to clarify the draft biological opinion and then would commence the stakeholder and public input process outlined above in paragraph 16. There is significant stakeholder interest in this process, as demonstrated by the 78,000 comments on EPA's draft biological evaluations and the analyses are extremely complex and technical. Given the level of interest and complexity of the issues, we cannot provide precise time estimates for the various processes identified in paragraph 16, but we estimate that NMFS and EPA will be able to conclude this process in sufficient time to allow NMFS to issue its final biological opinion by December 31, 2019. NMFS's biological opinion must be based on the administrative record before the agency, and if information is modified or augmented by EPA, NMFS must take those changes into account.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed this ninth day of November 2017.

Samuel D. Rauch, III
Deputy Assistant Administrator for Regulatory Programs
National Marine Fisheries Service

UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF WASHINGTON

NORTHWEST CENTER FOR ALTERNATIVES TO PESTICIDES, *et al.* *Plaintiffs*, v. NATIONAL MARINE FISHERIES SERVICE, *Federal Defendant.*	CASE NO. 07-1791-RSL **DECLARATION OF MARIETTA ECHEVERRIA**

I, Marietta Echeverria, state the following:

1. I declare that the following statements are true and correct to the best of my knowledge and belief and are based on either my personal knowledge, my review of information contained in the records provided to this Court or evaluations of such records supplied by current U.S. Environmental Protection Agency ("EPA" or the "Agency") employees.

2. I am the Director of the Environmental Fate and Effects Division ("EFED") in EPA's Office of Pesticide Programs ("OPP"). I have worked for EPA for 15 years. I have served in various positions within EPA, including Physical Scientist, Team Leader, and Branch Chief in EFED; and Senior Advisor and Branch Chief in the Registration Division ("RD"). I have been the Director of EFED since November 2016.

3. EFED is the division assigned with the responsibility for assessing the ecological

risk and environmental fate of both new and existing conventional pesticides under the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"). Part of this responsibility includes evaluating effects to species listed as threatened or endangered ("listed species") under the Endangered Species Act ("ESA") and preparing the biological evaluations that EPA provides to the National Marine Fisheries Service ("NMFS") and the Unites States Fish and Wildlife Service ("FWS") (collectively "Services") when it consults with the Services on pesticide actions that "may affect" listed species or their designated critical habitat. EPA's consultation obligations under the ESA involve extremely complex scientific assessments because rather than addressing effects of a discrete project at a specific location, EPA's pesticide registration actions effectively address the entire United States and therefore involve the potential for effects to hundreds of listed species in numerous and varying aquatic and terrestrial habitats.

4. Pursuant to a stipulation and order entered by this Court on May 21, 2014 ("the May 2014 Order"), and a parallel stipulation in *Center for Biological Diversity v. United States Fish and Wildlife Service*, No. 3:11-cv-5108-JSW (N.D. Cal., July 28, 2014) (Exhibit 1), the Services agreed to complete nationwide consultations on FIFRA pesticide registrations for the insecticides chlorpyrifos, diazinon and malathion by December 31, 2017.[1] These consultations represent the initial set of nationwide consultations being conducted in furtherance of the April 30, 2013 National Academy of Sciences (NAS) recommendations to EPA and the Services for conducting consultations on pesticide registration actions. And, in fact, they represent the first set of nationwide consultations ever conducted between EPA and the Services on FIFRA pesticide registrations. Prior to these consultations, the only consultations on FIFRA actions

[1] The settlement agreement in *Center for Biological Diversity v. United States Fish and Wildlife Service*, No. 3:11-cv-5108-JSW (N.D. Cal.) provides, in the alternative, for negotiations concerning potential regional consultations to the extent FWS does not issue a nationwide biological opinion before December 31, 2017.

completed between EPA and the Services had addressed a subset of the EPA's registration action at issue, or a subset of the species that could potentially be affected by EPA's registration action. Given EPA's obligation to complete the reevaluation of all existing pesticides (which includes all approved uses of such pesticides) under the registration review provisions of section 3(g) of FIFRA, EPA and the Services recognized the need for ESA consultations addressing all use of these pesticides across the country. Addressing this obligation would be unlike any other pesticide consultations EPA and the Services had previously conducted. In light of the complex and novel nature of the undertaking, the agreed upon December 2017 deadline for completing our consultations has proven challenging.

5. While the May 2014 Order does not specifically address EPA's and NMFS' internal time lines for completing the steps necessary to issue the biological opinions by December 2017, these steps were laid out by EPA and the Services in connection with the stipulation in the *Center for Biological Diversity* identified in above in paragraph 4. EPA and the Services provided the parties in that matter with EPA's and the Services' tentative milestones (the "Milestone document") (See Exhibit 2) for completing the consultation process, including EPA's planned dates for submitting its biological evaluations to the Services to commence consultation, as well as the Services' dates for developing draft biological opinions for public comment and for issuing final biological opinions.

6. In the Milestone document, EPA estimated that it would submit its biological evaluations for chlorpyrifos, diazinon and malathion to initiate consultation to FWS and NMFS by March 2016. While EPA understood when it started developing the biological evaluations that they would be of greater scope and complexity than any such documents that EPA/OPP had previously developed, the nature and extent of the undertaking, including the extent of public

comments, greatly exceeded EPA's expectations. The biological evaluations for the three insecticides address the potential effects of over 100 discrete uses on the over 1800 listed threatened and endangered species nationwide (including effects to any designated critical habitat for such species) and over 10,000 pages each. When EPA issued its draft biological evaluations for comments in April, 2016, EPA received comments from over 70,000 individuals (which included pesticide registrants, growers, food processors, environmental organizations, academics, various governmental entities as well as unaffiliated members of the public). While most of the comments were form letters, approximately 120 raised detailed scientific points requiring significant EFED review. EPA's final biological evaluations for chlorpyrifos, diazinon and malathion are available at https://www.epa.gov/endangered-species/implementing-nas-report-recommendations-ecological-risk-assessment-endangered-and.

7. As a result of the magnitude of the undertaking and the comments received, EPA's final biological evaluations were not issued until January 2017, approximately 9 months beyond the date EPA and the Services had previously estimated in the Milestone document, giving the Services significantly less time than previously estimated for the completion of their biological opinions that are to be based on the EPA biological evaluations.

8. As provided in the Milestone document, EPA and the Services anticipate releasing draft biological opinions for the public in advance of developing any final biological opinions. While the ESA and the Services' consultation regulations do not require the Services to issue draft biological opinions for public comment, given the broad extent of public interest in the evaluation and licensing of pesticides for use across the country, Congress, EPA and the Services have all agreed that meaningful public participation is a critical part of the consultation process on pesticide actions under FIFRA. Specifically, Section 10013 of the Agricultural Act

of 2014 (P.L. 113-79) directed EPA, the Services and USDA to, among other things, develop a report to inform Congress of specific actions that have been and will be taken to "ensure public participation and transparency in the development of reasonable and prudent alternatives and reasonable and prudent measures." Because reasonable and prudent alternatives and reasonable and prudent measures can be among the most critical elements of a biological opinion, it is clear that Congress anticipated that EPA and the Services would provide opportunities for public involvement.

9. EPA and the Services have addressed that Congressional directive by developing a "stakeholder" process that specifically calls for EPA to receive public comments on draft Service biological opinions and to allow the Services to address those comments before completing any final biological opinions addressing pesticide registration actions under FIFRA. In a document entitled Enhancing Stakeholder Input in the Pesticide Registration Review and ESA Consultation Processes and Development of Economically and Technologically Feasible Reasonable and Prudent Alternatives (available at https://www.regulations.gov/document?D=EPA-HQ-OPP-2012-0442-0038), EPA explained that,

> [t]he Services will provide EPA with the draft biological opinion for their review. EPA will make the draft biological opinion available for public comment. The public comment period provides another opportunity for stakeholders to provide valuable input on [Reasonable and Prudent Alternatives, Reasonable and Prudent Measures], and terms and conditions, as well as to provide/suggest/propose alternate risk reduction measures that accomplish the same protection goals but may be easier/less costly for the grower/user community to implement. All comments will be submitted to EPA, although the applicant may send a copy of its comments directly to the Service. EPA will organize the comments and highlight those of particular note and provide them to the Services.
>
> During the public comment period, EPA and the Services, supported by USDA, will solicit input from growers and other stakeholders on any

> technologically and economically feasible approaches that minimize the impact on growers and that allow them to meet their pest control needs while achieving the necessary protection goals to avoid jeopardy to threatened and/or endangered species. In particular, this process should offer stakeholders an opportunity to provide data and to identify practical considerations that affect the viability of different options for mitigating risks to species. EPA will provide a key role by focusing affected entities on the availability of the draft biological opinion and timeframes for submission of input.
>
> Upon receipt of the organized public comments from EPA, each Service will prepare a document for their respective opinions, where applicable, and include it in the administrative record that addresses how comments were considered and, if appropriate, how the final document was modified to address the comments. Each Service will include this document in their respective administrative records and will provide it to EPA. Both the Services and EPA will make the document available to the public upon request.

10. Given this document and the direction from Congress clearly indicating that the agencies should ensure that opportunities exist for public input on the measures the Services may put forth in biological opinions addressing pesticide registration actions, EPA believes that NMFS should have the time necessary to provide EPA with a draft biological opinion in order to allow EPA to publish the draft opinion for public comment and for NMFS to carefully consider the comments it receives.

11. EPA believes, however, that the agencies will reasonably need an additional year before EPA publishes the draft NMFS biological opinion for public comment. This time frame is necessitated both by the extended amount of time that was needed to finalize the biological evaluations and send them to NMFS, as outlined above in paragraphs five through seven, and to address issues with respect to the agencies' assessment methodologies raised during interagency discussions and by stakeholders during the public comment period. It is important to reiterate that the biological opinions on chlorpyrifos, diazinon and malathion represent the first nationwide consultations on pesticide registrations that EPA and the Services have ever undertaken and are also the first opinions being completed pursuant to methodologies

implementing the 2013 NAS report recommendations. These consultations were intended to be pilot consultations that would actually result in the development and refinement of the methodologies through an iterative process. Given where the agencies are in the consultation process, EPA expects the additional year would be divided into an initial six months for NMFS to provide a draft of its opinion to EPA and an additional six months for EPA to provide feedback to NMFS, and for NMFS to consider EPA's feedback and complete a draft for EPA to publish for comment.

12. With respect to EPA's part of the public comment process, once NMFS provides EPA with its draft biological opinion for public comment, EPA would then take steps to post the document(s) on its website and receive comment through the Regulations.gov website. After the close of the comment period, EPA would then compile the comments received, highlight significant comments, and provide them to the Services. EPA estimates that its role in this process would take approximately 180-240 days to complete, which includes development and posting of web materials informing the public that the comment period is open, a 60-day public comment period (which may be extended if EPA determines that an extension request is justified in light of the length and/or complexity of the biological opinion). This timeframe is also intended to accommodate time for EPA to develop its response to NMFS if EPA concludes that the draft biological opinion does not adequately address any issues raised by EPA earlier in the consultation process.

Pursuant to 28 U.S.C. Section 1746, I declare under penalty of perjury that to the best of my knowledge the foregoing is true and correct. Executed on this 8th day of November, 2017.

Marietta Echeverria

Marietta Echeverria
Director of the Environmental Fate and Effects Division
Environmental Protection Agency

Message

From: Noguchi, George [george_noguchi@fws.gov]
Sent: 2/23/2018 10:47:47 PM
To: Shultz, Gina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userd6a2f351]; Craig Aubrey [craig_aubrey@fws.gov]; Echeverria, Marietta [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=36c56b7169144626bd6aadea25992d4e-Marietta Echeverria]; Pease, Anita [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dbbef4b4951144499885d4cdf88d46d0-Anita Pease]; Anderson, Brian [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce7d6e5ad2e94b3f8f5ac4d839a6c268-Brian Anderson]; Perry, Tracy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ffd9b082a6484fe8a70cade93a68466c-Tracy L Perry]; Villanueva, Philip [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93adaf07438a402faa959bb6d04e7d86-Villanueva, Phillip]; cathy.tortorici@noaa.gov [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1bdaaff0c14a4264abc82f1468af694d-cathy.tortorici@noaa.gov]; Kunickis, Sheryl - OSEC [Sheryl.kunickis@osec.usda.gov]; Corbin, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1db182663b134e46b3fec580f8e0b5f2-Mark Corbin]; Ashley Stilson [ashley_stilson@fws.gov]
Subject: Updated Agenda for the Pesticide usage meeting
Attachments: Pesticide Usage Meeting Agenda _2_21_2018 final II.docx

Greetings,

I've attached an updated agenda for Mondays pesticide usage meeting.

See you next week,

George

--
George Noguchi, Ph.D.
Environmental Contaminants Specialist
US Fish and Wildlife Service
Ecological Services Program
MS: ES
5275 Leesburg Pike
Falls Church, VA 22041-3803
(Phone) 703-358-1857
(Fax) 703-358-1800

Message

From: Ashfield, Patrice [patrice_ashfield@fws.gov]
Sent: 2/22/2018 9:27:48 PM
To: Ashley Stilson [ashley_stilson@fws.gov]; Aubrey, Craig [craig_aubrey@fws.gov]; Anderson, Brian [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce7d6e5ad2e94b3f8f5ac4d839a6c268-Brian Anderson]; cathy.tortorici@noaa.gov [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1bdaaff0c14a4264abc82f1468af694d-cathy.tortorici@noaa.gov]; Sims, Diann [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7ca5706c9da345c5af43f0899cf3a8df-Diann Sims]; Shultz, Gina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userd6a2f351]; Guilaran, Yu-Ting [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a698774e93e34a2b9181d4b3032b8a32-ytguilar]; Echeverria, Marietta [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=36c56b7169144626bd6aadea25992d4e-Marietta Echeverria]; Villanueva, Philip [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93adaf07438a402faa959bb6d04e7d86-Villanueva, Phillip]; Sheryl Kunickis [Sheryl.Kunickis@osec.usda.gov]; Perry, Tracy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ffd9b082a6484fe8a70cade93a68466c-Tracy L Perry]
Subject: Final Agenda, Parking and Shuttle Information
Attachments: Directions_USFWS_Headquarters and parking (1).pdf; HQ VisitorInfoPacket_Pesticides Use & Usage Meeting 2018-02-26.docx; SkylineShuttleBallstonPickup with added info 20180222.pptx; MIB to Skyline Shuttle Schedule.docx; Pesticide Usage Meeting Agenda _2_21_2018 final .docx

Dear All-
Pls forward to your folks. This information will also be attached to our calendar invite. Remember to check in with the guards for a visitor badge.

Thanks. See you Monday!

Patrice M. Ashfield
Branch Chief for National Pesticide Consultations
Headquarters, Fish and Wildlife Service
5275 Leesburg Pike, MS:ES
Falls Church, VA 22041
(703) 358-2478 office

Directions to USFWS Headquarters

Skyline Technology Center

5275 Leesburg Pike, Falls Church, VA 22041-3803

From I-395 (N or S)

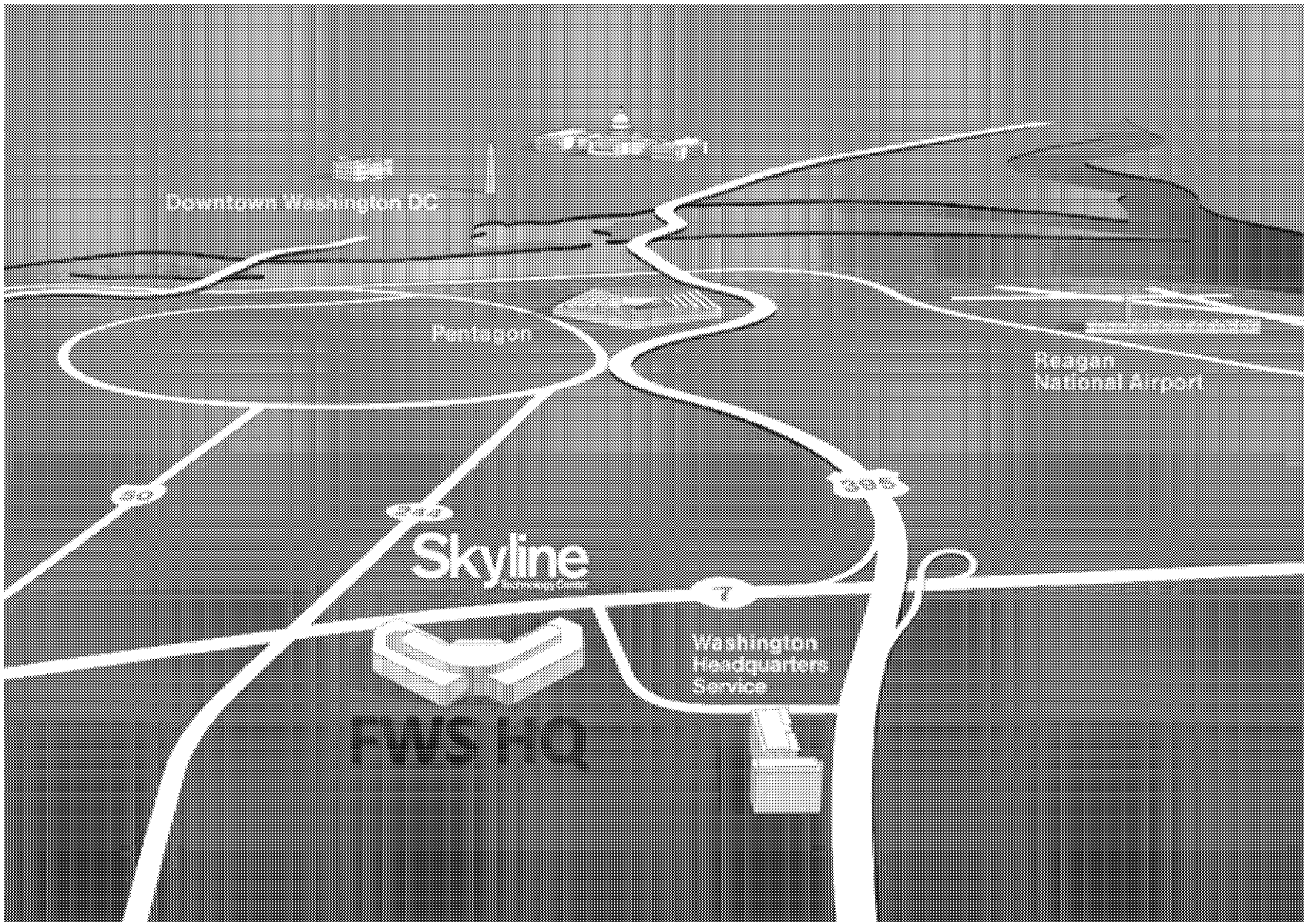
- Take 395 (Henry G. Shirley Memorial Hwy) to Exit 5 (VA-7 W/King St) in Virginia.
- Take exit 5 (VA-7 W/King St) from 395
- Continue on VA-7 W/King St for about 1.6 miles until you cross over S. George Mason Drive.
- After crossing S. George Mason Drive, you will see a Target on your left.
- Skyline Technology Center is on the left, right after the Target, and can be accessed from the next two lights.

From Tyson's Corner

- Take exit #50A-B/US-50/US-29/Arlington Blvd/Lee Hwy/Fairfax/Arlington onto Arlington Blvd (US-50 E)
- Bear right toward VA-338/Falls Church/VA-7/Alexandria
- Continue on Arlington Blvd
- Bear right onto Leesburg Pike (VA-7 E) toward Alexandria
- Your destination on Leesburg Pike (VA-7 E) is on the right.

Visitor / Daily Parking: Visitor / daily parking is located in the surface parking lots behind 5205-5203-5201 Leesburg Pike or in front of 5111-5109 Leesburg Pike. The cost is $5 for the first hour and $10 for the first two hours. After two hours, the cost is the daily maximum of $20.

To Bailey's Crossroads
Seminary Road
FWS
Visitor Parking
One Skyline Place
Two Skyline Place
Three Skyline Place
Four Skyline Place
Five Skyline Place
Six Skyline Place
Visitor Parking
One Skyline Tower
Shopping Mall Parking
Leesburg Pike (Route 7)
George Mason Drive
George Mason Drive


Downtown Washington DC
Pentagon
Reagan
National Airport
Skyline
Washington
Headquarters
Service
FWS HQ

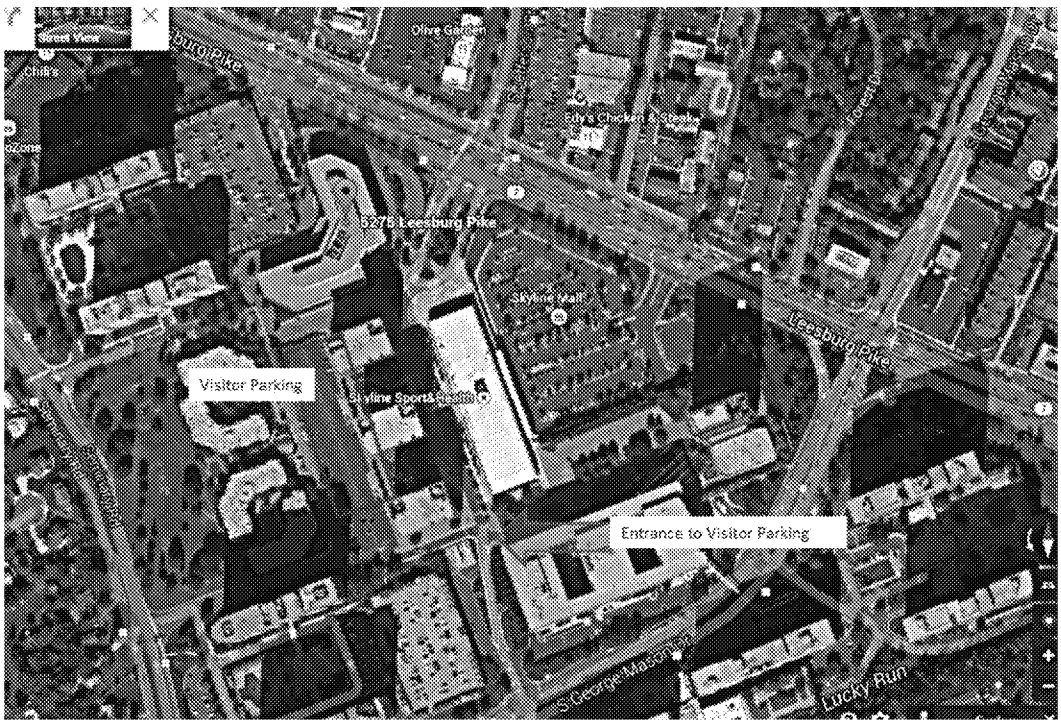

Washington DC
Skyline (FWS HQ)
Falls Church
Arlington County
Alexandria
Fairfax County
Springfield
Lorton
Quantico
Ft. Belvoir
NGA
WHS
PTO
EPA
NSF
DARPA
MDA
State Dept.
Pentagon
TSA
DEA
US Marshals
Medical Commands
Washington Reagan National Airport
Tysons Corner
McLean
Vienna
Merrifield
Annandale
Huntington
Mount Vernon
Silver Spring
Bethesda
Montgomery County
Prince George's County
Crystal City
Ocean Hill
Virginia
4 mile
8 mile
495
66
395
270
355
95

Use and Usage Pesticides Meeting

Visitor Information

February 2018

U.S. Fish and Wildlife (FWS, Service) Headquarters building is located at 5275 Leesburg Pike, Falls Church, VA 22041. The Headquarters building can be accessed from two major roads (Leesburg Pike / Route 7 and S. George Mason Drive). Visitor parking is next to HQ and costs $20 per day. HQ is also accessible by public transportation and shuttle. A free shuttle service runs from Ballston, close to our previous Arlington Square location.



Directions to Visitor Parking

From Leesburg Pike:

- Turn south onto S. Jefferson Street and go UP the middle ramp (the 5275 building will be straight ahead).
- Turn left in front of the Subway restaurant and follow the signs to visitor parking.
- Turn right into visitor parking lot.

From S. George Mason Drive:

- Turn north at the light where there's a sign by the side of the road that says Skyline Office Complex and Visitor Parking. If you're coming south on George Mason, it's a right at the second light after crossing Leesburg Pike. If you're coming north from Seminary Road, it's a left at the first light.
- Go UP the ramp and then turn left into the visitor parking lot.

Visitor / Daily Parking is located in the surface parking lots behind 5205-5203-5201 Leesburg Pike or in front of 5111-5109 Leesburg Pike. The cost is $5 for the first hour and $10 for the first two hours. After two hours, the cost is the daily maximum of $20.

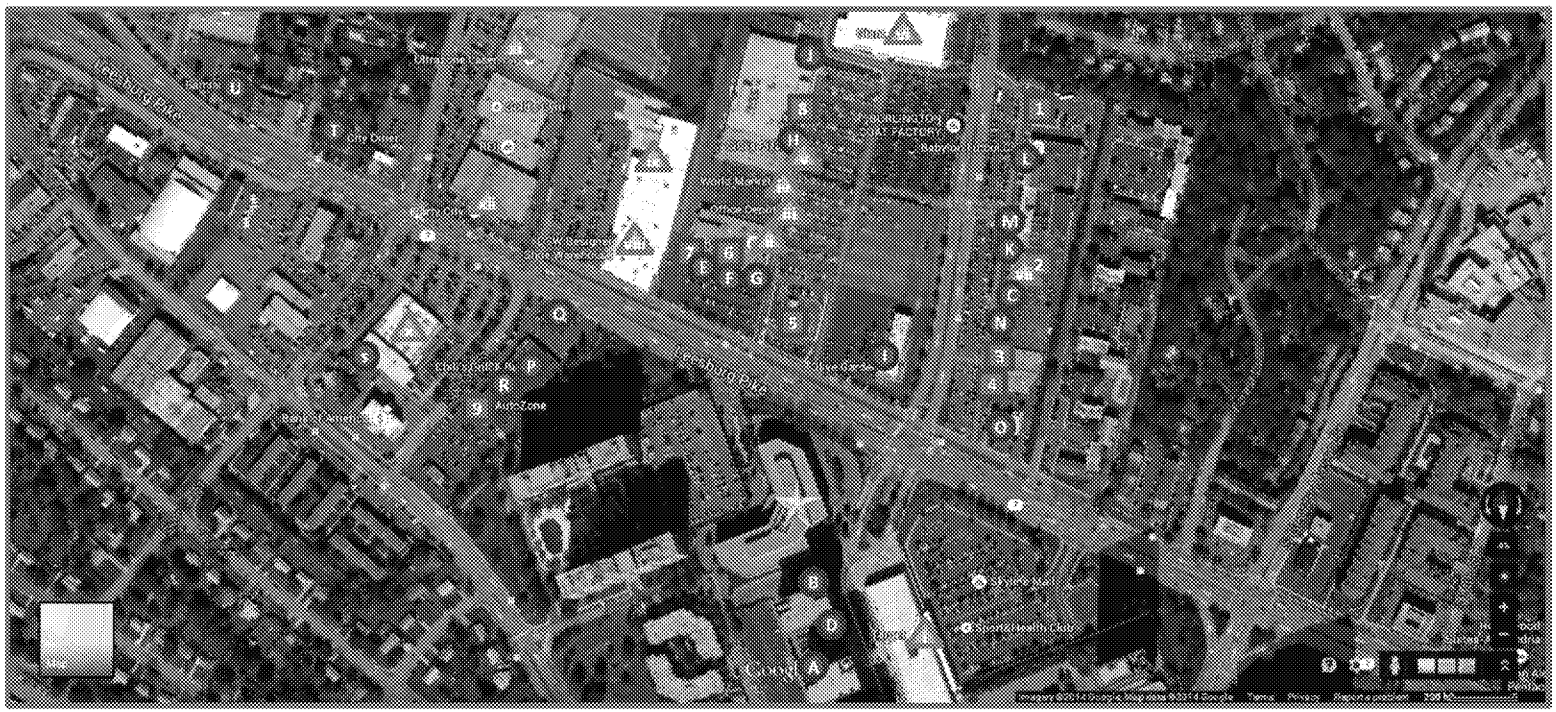
Entering the Building

Visitors must be screened prior to accessing FWS Headquarters space and escorted to the conference room.

a. Please arrive at least 10 minutes early.
b. Visitors must check in with the guard stationed at the front desk in the building lobby and complete required x-ray and / or magnetometer screening. A Fish and Wildlife Service employee will be on standby to escort guests to the conference room.
c. If any visitor is legally armed as part of his / her official position (i.e., OLE personnel), the visitor must clearly indicate this to the FPS guards upon check in. Please notify the event organizers in advance if this is the case (provide your name and reason for bringing firearm into the building) so they can notify the guards.

U.S. Fish and Wildlife Headquarters
"Neighborhood" Amenities Map

This listing does not imply an advertisement or endorsement of these establishments



U.S. Fish and Wildlife Headquarters

Restaurants

Services

Shopping

Neighborhood amenities listed as "off map" on the following pages are further north on Leesburg Pike

Last Updated 7/15/2014

U.S. Fish and Wildlife Headquarters

Local Restaurants

This listing does not imply an advertisement or endorsement of these establishments

Walking Distance

- A Fresh Chop Chop Café
- B C Subway (The Subway in location "B" has closed)
- D The Perfect Pita
- E Quiznos
- F Einstein Bros Bagels
- G Starbucks
- H CiCi's Pizza
- I Olive Garden and next door is Long Horn Steakhouse
- J Great American Steak & Buffet
- K Z Kabob
- L Bamboo Buffet
- M Dairy Queen
- N Pho Golden Star
- O Edy's Chicken & Steak Restaurant
- P Chili's Grill & Bar
- Q The Chicken Place
- R Vocelli Pizza

New Restaurants in Skyline 7 Building:
- Paneras
- Buffalo Wildwings
- District Taco

Driving Distance

- S Athens Restaurant
- T City Diner
- U Bamain Restaurant
- V Panera ***** Off Map***
- W Qdoba ***** Off Map***

Last Updated 7/15/2014

U.S. Fish and Wildlife Headquarters

Local Services

This listing does not imply an advertisement or endorsement of these establishments

Walking Distance

1. Capital One Bank
2. FedEx
3. CVS Pharmacy
4. Verizon Wireless
5. PNC Bank
6. Bailey's Cleaners
7. Hour Eyes
8. Advanced AutoParts
9. AutoZone

Last Updated 7/15/2014

U.S. Fish and Wildlife Headquarters

Local Shopping

This listing does not imply an advertisement or endorsement of these establishments

Walking Distance

Target

Home Goods

World Market

Office Depot

Burlington Coat Factory

Giant Supermarket

Party Depot

Driving Distance

Designer Shoe Warehouse

Babies 'R' Us

Toys 'R' Us

Tuesday Morning

Party City

Best Buy ***** Off Map**

Trader Joe's ***** Off Map**

Bed, Bath, & Beyond ***** Off Map**

Ross Dress for Less ***** Off Map**

Marshalls ***** Off Map**

Dick's Sporting Goods ***** Off Map**

Last Updated 7/15/2014

Visitors may use the shuttles to / from FWS Headquarters that run from the Main Interior Building to Farragut North Metro station, and Skyline. Drivers check riders' IDs when boarding shuttles departing from FWS Headquarters to the Main Interior Building and Farragut North Metro stop. Visitors without a DOI PIV card must have an email from their host program in order to ride these shuttles.

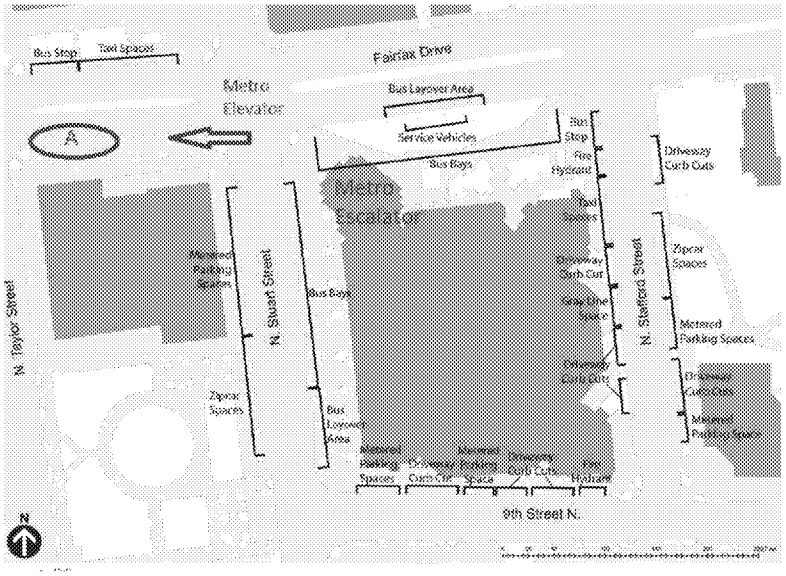
Main Interior Building Shuttle Schedule

Filter:

Bus	MIB 18th & C	Farragut N. Metro	Skyline Seven 5275 Leesburg Pike
Bus 1			7:25 AM **First pickup Bus 1 Service**
Bus 2	7:25 AM	7:35 AM	7:55 AM
Bus 1	7:55 AM		8:25 AM
Bus 2	8:25 AM	8:35 AM	8:55 AM
Bus 1	8:55 AM		9:25 AM
Bus 2	9:25 AM		9:55 AM
Bus 1	9:55 AM		10:25 AM
Bus 2	10:25 AM		10:55 AM
Bus 1	10:55 AM **Drop only**		**Lunch**
Bus 2	11:35 AM		11:55 AM
Bus 1	11:55 AM **Pickup only**		12:25 PM
Bus 2	12:25 PM **Drop only**		**Lunch**
Bus 1	12:55 PM		1:25 PM
Bus 2	1:25 PM **Pickup only**		1:55 PM

Bus 1	1:55 PM		2:25 PM
Bus 2	2:25 PM		2:55 PM
Bus 1	2:55 PM		3:25 PM
Bus 2	3:25 PM		4:05 PM
Bus 1	3:55 PM		4:35 PM
Bus 2	4:30 PM	4:40 PM	5:10 PM
Bus 1	5:05 PM		5:35 PM
Bus 2	5:30 PM	5:40 PM	6:10 PM
Bus 1	6:05 PM		6:35 PM
Bus 2	6:30 PM	6:40 PM	7:10 PM **Drop only - End of Bus 2 service**
Bus 1	7:05 PM **Drop only - End of Bus 1 service**		

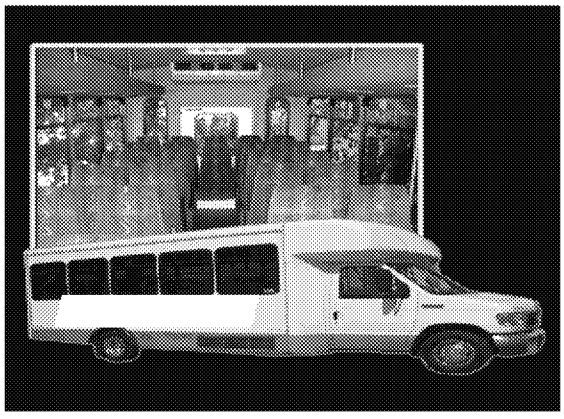
SKYLINE SHUTTLE BUS RIDERS



Beginning Monday, July 13, all Skyline Shuttle Buses will pick up and drop off at the "A" Shuttle Bus Bay located on Fairfax Drive.

Bay A: Skyline Shuttle Stop

Skyline Shuttle Buses



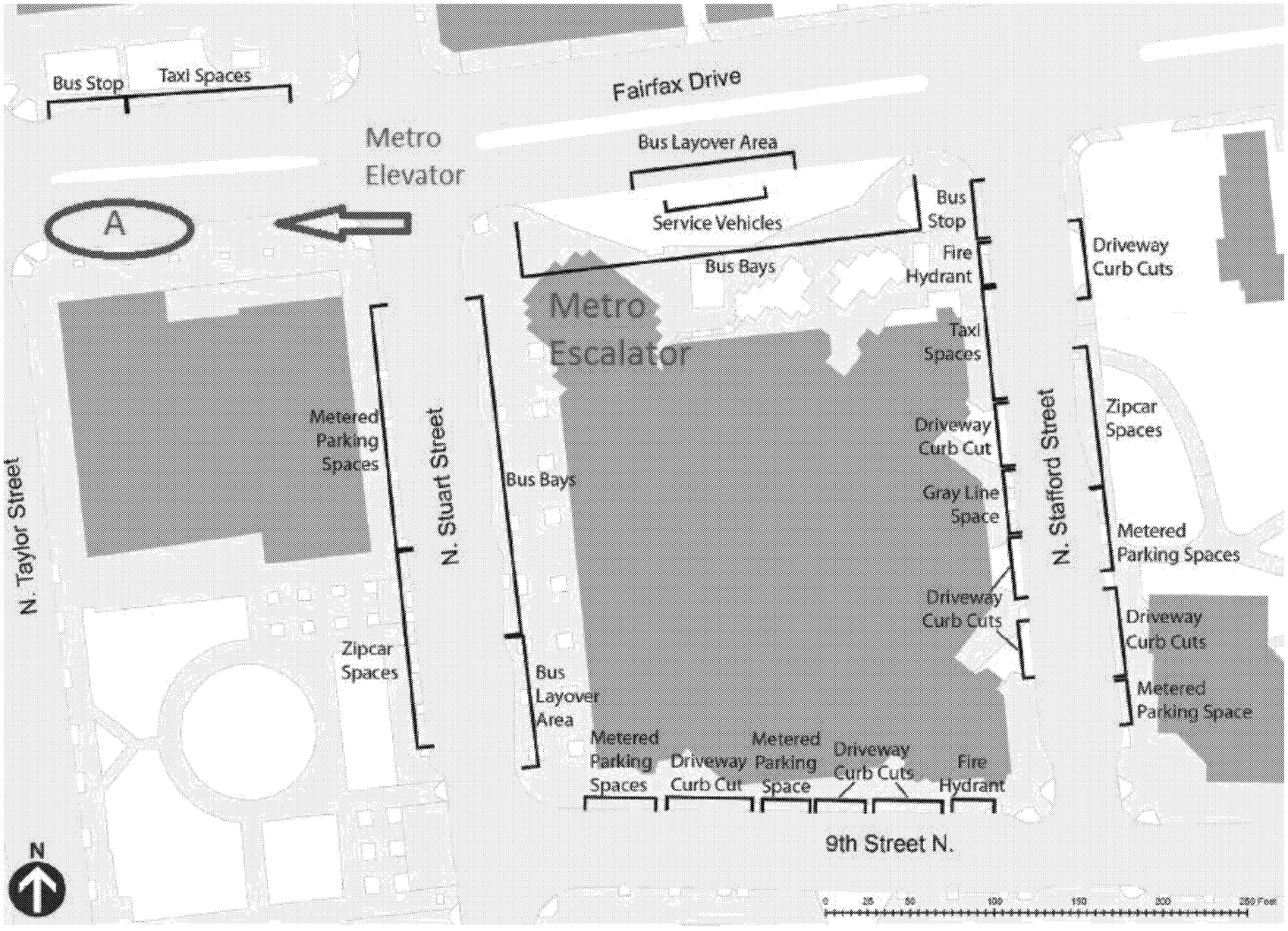
Please look for a blue "Skyline Metro Shuttle" or the white "Chariots for Hire" shuttle. FYI: There are multiple shuttle services that utilize this drop off and pick up location (including at least one other that also utilizes "Chariots for Hire" vans). Please ask the shuttle driver as you board to make sure it is going to the Skyline Building complex.

The Ballston Skyline Shuttle service stops at two locations in the Skyline Complex:
- Skyline Building 4
- Skyline Building 7 (FWS HQ)

Skyline Shuttle Schedule

[illegible]	[illegible]	[illegible]
6:00 AM **Initial Pick-Up**	6:20 AM	6:25 AM
6:15 AM	6:35 AM	6:40 AM
6:30 AM	6:50 AM	6:55 AM
6:45 AM	7:05 AM	7:10 AM
7:00 AM	7:20 AM	7:25 AM
7:15 AM	7:35 AM	7:40 AM
7:30 AM	7:50 AM	7:55 AM
7:45 AM	8:05 AM	8:10 AM
8:00 AM	8:20 AM	8:25 AM
8:15 AM	8:35 AM	8:40 AM
8:30 AM	8:50 AM	8:55 AM
8:45 AM	9:05 AM **Drop Only**	9:10 AM **Drop Only**
9:00 AM	9:20 AM	9:25 AM
9:30 AM	9:50 AM	9:55 AM
10:00 AM	10:20 AM	10:25 AM
10:30 AM	10:50 AM	10:55 AM
11:00 AM	11:20 AM	11:25 AM
11:30 AM	11:50 AM	11:55 AM
12:00 PM	12:20 PM	12:25 PM
12:30 PM	12:50 PM	12:55 PM
1:00 PM	1:20 PM	1:25 PM
1:30 PM	1:50 PM	1:55 PM
2:00 PM	2:20 PM	2:25 PM
2:30 PM	2:50 PM	2:55 PM
3:00 PM	3:20 PM	3:25 PM
3:30 PM	3:50 PM	3:55 PM
3:45 PM	4:05 PM	4:10 PM
4:00 PM	4:20 PM	4:25 PM
4:15 PM	4:35 PM	4:40 PM
4:30 PM	4:50 PM	4:55 PM
4:45 PM	5:05 PM	5:10 PM
5:00 PM	5:20 PM	5:25 PM
5:15 PM	5:35 PM	5:40 PM
5:30 PM	5:50 PM	5:55 PM
5:45 PM	6:05 PM	6:10 PM
6:00 PM	6:20 PM	6:25 PM
6:15 PM **Drop Only**		
6:30 PM **Drop Only**		
6:45 PM **Drop Only**		

SKYLINE SHUTTLE BUS RIDERS



Beginning <u>Monday, July 13</u>, all Skyline Shuttle Buses will pick up and drop off at the "A" Shuttle Bus Bay located on Fairfax Drive.

Bay A: Skyline Shuttle Stop

Message

From: Ashfield, Patrice [patrice_ashfield@fws.gov]
Sent: 2/22/2018 3:46:47 PM
To: Ashley Stilson [ashley_stilson@fws.gov]; Aubrey, Craig [craig_aubrey@fws.gov]; Anderson, Brian [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce7d6e5ad2e94b3f8f5ac4d839a6c268-Brian Anderson]; cathy.tortorici@noaa.gov [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1bdaaff0c14a4264abc82f1468af694d-cathy.tortorici@noaa.gov]; Sims, Diann [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7ca5706c9da345c5af43f0899cf3a8df-Diann Sims]; Shultz, Gina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userd6a2f351]; Guilaran, Yu-Ting [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a698774e93e34a2b9181d4b3032b8a32-ytguilar]; Echeverria, Marietta [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=36c56b7169144626bd6aadea25992d4e-Marietta Echeverria]; Villanueva, Philip [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93adaf07438a402faa959bb6d04e7d86-Villanueva, Phillip]; Sheryl Kunickis [Sheryl.Kunickis@osec.usda.gov]; Perry, Tracy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ffd9b082a6484fe8a70cade93a68466c-Tracy L Perry]
Subject: Final Draft Agenda
Attachments: Draft agenda for pesticide use meeting_2_21_2018 final (2).docx

Dear All-
Pls let me know if this works as a final agenda. I added 5 minutes for Saman to introduce herself and her process and I added discussion time per topic. Also, as Gina mentioned, if we need more time for the agriculture usage data discussion, we can adjust our timing on Monday.

After I receive either your edits or thumbs up, I will send the Final version to this team COB today.

Thanks Everyone!

Patrice M. Ashfield
Branch Chief for National Pesticide Consultations
Headquarters, Fish and Wildlife Service
5275 Leesburg Pike, MS:ES
Falls Church, VA 22041
(703) 358-2478 office

Message

From: Cathy Tortorici - NOAA Federal [cathy.tortorici@noaa.gov]
Sent: 1/11/2018 2:21:35 PM
To: Shultz, Gina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userd6a2f351]; Craig_Aubrey@fws.gov; Patrice Ashfield [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user1f5a6e17]; George Noguchi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userbe760c8b]; Echeverria, Marietta [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=36c56b7169144626bd6aadea25992d4e-Marietta Echeverria]; Villanueva, Philip [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93adaf07438a402faa959bb6d04e7d86-Villanueva, Phillip]; Anderson, Brian [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce7d6e5ad2e94b3f8f5ac4d839a6c268-Brian Anderson]; Kunickis, Sheryl [Sheryl.Kunickis@osec.usda.gov]
Subject: Pesticides - NCAP withdrawal of motion
Attachments: EXECUTIVE_OFFICE-#387821-v1-notice_of_withdrawal_of_cross-motion.PDF

Dear all -

As I mentioned this morning - Plaintiffs have withdrawn their cross-motion for release of documents relating to the BiOp and pesticides consultation. Notice attached.

Cathy T.

--
Cathy Tortorici
Chief, ESA Interagency Cooperation Division
Office of Protected Resources
NOAA's National Marine Fisheries Service
1315 East-West Highway
Silver Spring, MD 20910
(w) 301.427.8495
(c) 301.602.2193
cathy.tortorici@noaa.gov

Honorable Robert S. Lasnik

UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF WASHINGTON

NORTHWEST COALITION FOR ALTERNATIVES TO PESTICIDES, PACIFIC COAST FEDERATION OF FISHERMEN'S ASSOCIATIONS, and INSTITUTE FOR FISHERIES RESOURCES, Plaintiffs, v. NATIONAL MARINE FISHERIES SERVICE, Defendant.	No. 07-cv-1791-RSL NOTICE OF WITHDRAWAL OF CROSS-MOTION (Dkt. 54)

On January, 9, 2018, defendants provided plaintiffs an Endangered Species Act biological opinion regarding EPA's registration of the pesticides chlorpyrifos, diazinon, and malathion, eliminating the need for plaintiffs to obtain the documents sought in the cross-motion OPPOSITION TO MOTION TO AMEND AND CROSS-MOTION FOR RELEASE OF KEY DOCUMENTS (Dkt. 54). Accordingly, plaintiffs hereby withdraw the cross-motion.

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Earthjustice
705 Second Ave., Suite 203
Seattle, WA 98104
(206) 343-7340

Respectfully submitted this 10th day of January, 2018.

STEPHEN D. MASHUDA, WSB #36968
PATTI A. GOLDMAN, WSBA # 24426
Earthjustice
705 Second Avenue, Suite 203
Seattle, WA 98104-1711
Ph.: (206) 343-7340
Fax: (206) 343-1526
smashuda@earthjustice.org
pgoldman@earthjustice.org

Attorneys for Plaintiffs

Message

From: Anderson, Brian [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CE7D6E5AD2E94B3F8F5AC4D839A6C268-BRIAN ANDERSON]
Sent: 2/15/2018 10:11:42 PM
To: Patrice Ashfield [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user1f5a6e17]
CC: Echeverria, Marietta [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=36c56b7169144626bd6aadea25992d4e-Marietta Echeverria]; Sims, Diann [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7ca5706c9da345c5af43f0899cf3a8df-Diann Sims]; Miller, Wynne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8267862f7fea4782aec32ea5fec8c19c-wymiller]
Subject: Draft agenda for pesticide use meeting_2_15_2018.docx
Attachments: Draft agenda for pesticide use meeting_2_15_2018.docx

Hi Patrice,

Are you the right person to whom to send edits to the agenda? We have two additions at this time. Please feel free to give me a call if you have any questions.

Thanks

Brian

Message

From: Miller, Kayla [kayla_miller@fws.gov]
Sent: 6/23/2017 6:23:33 PM
To: Echeverria, Marietta [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=36c56b7169144626bd6aadea25992d4e-Marietta Echeverria]; Dumas, Richard [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=082146a785ef4acd8bad309466dd313a-Richard P. Dumas]; Pease, Anita [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dbbef4b4951144499885d4cdf88d46d0-Anita Pease]; Anderson, Brian [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce7d6e5ad2e94b3f8f5ac4d839a6c268-Brian Anderson]; Villanueva, Philip [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93adaf07438a402faa959bb6d04e7d86-Villanueva, Phillip]; Perry, Tracy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ffd9b082a6484fe8a70cade93a68466c-Tracy L Perry]; cathy.tortorici@noaa.gov [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1bdaaff0c14a4264abc82f1468af694d-cathy.tortorici@noaa.gov]; Kunickis, Sheryl - OSEC [sheryl.kunickis@osec.usda.gov]
CC: Shultz, Gina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userd6a2f351]; Patrice Ashfield [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user1f5a6e17]; Craig Aubrey [craig_aubrey@fws.gov]
Subject: Fish and Wildlife Service Settlement Agreement
Attachments: Pesticide Sec. 7 Settlement Agreements (1).pdf

Hello All,

As was discussed on the Senior Management phone call yesterday, attached is the Fish and Wildlife Service's settlement agreement for the original red legged frog agreement with the amendment.

Thank You,
Kayla Miller

--
Knauss Fellow 2017-2018
Special Assistant to the Deputy Assistant Director, Ecological Services
U.S. Fish and Wildlife Service

5275 Leesburg Pike
Falls Church, VA 22041-3803
703-358-1898

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

Center for Biological Diversity,

Plaintiff,

v.

United States Fish and Wildlife Service et al.,

Defendants,

and,

CropLife America,

Intervenor-Defendant.

Case No. 3:11-cv-5108-JSW

Stipulation Amending Original Stipulated Settlement and [~~Proposed~~] Order

Plaintiff Center for Biological Diversity (the "Center"), Defendants the United States Fish and Wildlife Service ("FWS"), Dan Ashe, in his official capacity as Director of the Fish and Wildlife Service, the United States Environmental Protection Agency ("EPA"), and Gina McCarthy, in her official capacity as Administrator of EPA (collectively, the "Parties"), by and through the undersigned counsel, state as follows:

Whereas, the Parties entered into a stipulated settlement that resolved the remaining disputed issues in this case, and the Court entered the terms of that settlement as an order and dismissed this case without prejudice (while retaining continuing jurisdiction to enforce its order), Docket No. 76 (Nov. 4, 2013) ("Original Stipulated Settlement");

Whereas, that settlement requires FWS to complete consultation with EPA under the Endangered Species Act ("ESA") (and pursuant to the applicable regulations) on the potential effects of seven pesticides on the California red-legged frog by November of 2015, Stipulated Settlement ¶¶ 1, 2;

Whereas, EPA, the United States Department of the Interior, the United States Department of Commerce, and the United States Department of Agriculture ("USDA") had previously asked the National Academy of Sciences ("NAS") to evaluate the differing risk assessment approaches used by these agencies to identify the potential effects of pesticides on threatened and endangered species;

Whereas, the NAS responded to that request on April 30, 2013 by issuing a report entitled "Assessing Risks to Endangered and Threatened Species from Pesticides" (the "NAS report");

Whereas, the NAS report suggests, *inter alia*, that EPA, FWS, and the National Marine Fisheries Service ("NMFS") take a common approach to assessing the potential effects of pesticides on threatened and endangered species to facilitate coordination among federal agencies;

Whereas, EPA, FWS, NMFS, and the USDA are now working in close cooperation to evaluate and implement the recommendations made by the NAS report;

Whereas, based on the findings in the NAS report and the work done so far by the agencies to implement the recommendations in that report, the Parties now agree that it would be more efficient for EPA and FWS to consult on the potential effects that pesticides at issue in this case have on threatened and endangered species nationwide, instead of limiting their consultation only to potential effects on the California red-legged frog;

Whereas, EPA and FWS are working to complete such nationwide consultations on five (5) of the pesticides at issue in this case as part of the nationwide endangered species assessments that EPA will be conducting in connection with registration review under the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA");

Whereas, those five (5) pesticides are carbaryl, chlorpyrifos, diazinon, malathion, and methomyl;

Whereas, EPA and FWS currently expect to complete nationwide ESA consultations for three (3) of the five pesticides listed above by December 31, 2017 and for the remaining two (2) pesticides by December 31, 2018;

Whereas, the Parties agree that it would be more efficient to conduct nationwide consultations, instead of consultations limited to the California red-legged frog, but the agencies still face significant challenges in implementing the recommendations of the NAS report and completing such nationwide consultations;

Whereas, the Parties have now devised this stipulation to amend the Original Stipulated Settlement so that FWS will have an opportunity to attempt to complete the nationwide consultations described above, but which will still require FWS to complete the original consultations on the California red-legged frog if it is not able to complete nationwide consultations (although the schedule for such California red-legged frog consultations would be extended);

Whereas, the Parties reserved the right to ask this Court to modify the Original Stipulated Settlement "because of the Service's ongoing actions to comply with the ESA, to meet the requirements of other federal agencies or departments, or to deal with circumstances not presently anticipated."

Stipulated Settlement ¶ 5; and,

Whereas, Intervenor-Defendant CropLife America takes no position on the relief sought by this stipulation;

Now, therefore, the Parties stipulate to amend the Original Stipulated Settlement as follows:

1. The consultation schedule set out in paragraph 2 of the Original Stipulated Settlement is hereby suspended to allow the Federal agencies to engage in the nationwide consultations described above in the "whereas" clauses.

2. No provision of this Stipulation requires (or shall be construed to require) FWS or EPA to conduct the nationwide consultations described above in the "whereas" clauses, and no provision of this Stipulation requires (or shall be construed to require) FWS or EPA to complete any such nationwide consultations on the schedule set out above in the "whereas" clauses.

3. While it is not obligated to do so, if FWS completes nationwide consultations on the effects of the five (5) pesticides listed above on the schedule set out above in the "whereas" clauses, then FWS shall be deemed to have discharged its obligations under the terms of the Original Stipulated Settlement in full.

4. Alternatively, if:

(a) FWS does not complete nationwide consultations on the five (5) pesticides listed above on the schedule set out above in the "whereas" clauses;

(b) FWS concludes (based on further review of these issues) that nationwide consultations are no longer appropriate; or,

(c) FWS does not complete the interim benchmarks on the

estimated schedule described below in Paragraph 5,

then:

(1) at the request of either the Center or the Federal Defendants, the Parties shall meet and confer at the earliest available opportunity to discuss whether it is appropriate for FWS to complete the consultations "on the potential effects of seven pesticides on the California red-legged frog" described in Paragraph 1 of the Original Stipulated Settlement and, if so, to discuss an appropriate revised schedule for those consultations based on the schedule set out in Paragraph 2 of the Original Stipulated Settlement; and,

(2) if the Parties are unable to reach agreement on that revised schedule within thirty (30) days of any such meeting and conference, either party may petition the Court to resolve the dispute and set a schedule for the remaining consultations "on the potential effects of seven pesticides on the California red-legged frog" described in Paragraph 1 of the Original Stipulated Settlement.

5. Within 30 days of the Court's approval of the Amended Stipulated Settlement, FWS and EPA shall provide the Center (and Intervenor-Defendant) with an estimated schedule, including interim benchmarks, for completing the nationwide consultations described above in the "whereas" clauses. That schedule will include estimated dates for EPA's preliminary risk assessments (which include the draft biological evaluation ("BE")), EPA's submittal of the BE to FWS, FWS's draft biological opinions, and FWS's final biological opinions for each of these pesticides. The parties recognize that this schedule will be a good faith estimate as of the date that it is provided, but that the schedule may be subject to change (based on factors including, but not limited to, variations in the estimated dates for data

submission, the volume of public comments, and unanticipated legal obligations), and that, as stated above in Paragraph 2, this schedule will not be binding or enforceable by the Court.

6. FWS shall provide the Center (and Intervenor-Defendant) with an update by conference call every four (4) months describing the status of these consultations.

7. Within 30 days of the Court's approval of the amended Stipulated Settlement, FWS shall issue a press release that alerts the public to the amended Stipulated Settlement and shall make the following modifications to the webpage created pursuant to the first paragraph in Section 3 ("Web-site Content") of the Original Stipulated Settlement: i) summarize the principal terms of this amended Stipulated Settlement; and ii) include a hyperlink to the full text of this amended Stipulated Settlement. As for the webpage created pursuant to the second paragraph in Section 3 ("Web-site Content") of the Original Stipulated Settlement, FWS shall work with EPA to include on an appropriate, easily accessible Federal government website publicly-available documents associated with the nationwide consultation processes for the pesticides that are the subject of this stipulation, as well as the pesticides that are subject to this case, including preliminary risk assessments, biological evaluations, draft biological opinions, and proposed decisions that are subject to public comment. The webpage shall post the documents or links to websites containing the documents within 14 days of the date they become publicly available.

8. The first and second sentences of Paragraph 15 of the Original Stipulated Settlement are amended to read, in their entirety: "Upon entry of this Stipulated Settlement, Plaintiff's complaint shall be dismissed without prejudice. Plaintiff resolves its Complaint as to the five active ingredients

carbaryl, chlorpyrifos, diazinon, malathion, and methomyl, but Plaintiff reserves the right to bring a new Complaint regarding the 59 other active ingredients." This Stipulation does not amend the third sentence of Paragraph 15 of the Original Stipulated Settlement, which remains in effect.

9. Provisions of the Original Stipulated Settlement that are not directly amended by this Stipulated Settlement shall remain in effect.

10. This Stipulation has no precedential value and shall not be used as evidence in litigation or in any other context.

PURSUANT TO STIPULATION, IT IS ORDERED that the Settlement executed by the Parties is hereby incorporated into this Order; and

IT IS FURTHER ORDERED that this Court shall have continuing jurisdiction to enforce this Order and the terms of the Settlement herein consistent with the terms of that agreement; and

IT IS FURTHER ORDERED that this case is hereby **DISMISSED** without prejudice.

Dated: July 28, 2014

Jeffrey S. White
United States District Judge

Respectfully submitted July 25, 2014,

SAM HIRSCH,

Acting Assistant Attorney General
United States Department of Justice
Environment & Natural Resources Division

SETH M. BARSKY, Section Chief
S. JAY GOVINDAN, Assistant Section Chief

/s/ James A. Maysonett

JAMES A. MAYSONETT, Senior Trial Attorney

Wildlife & Marine Resources Section
P.O. Box 7611, Washington D.C. 20044
(202) 305-0216, facsimile (202) 305-0275
james.a.maysonett@usdoj.gov

COUNSEL FOR FEDERAL DEFENDANTS

/s/ Collette Adkins Giese

COLLETTE ADKINS GIESE (MN Bar # 035059X)
JUSTIN AUGUSTINE (CA Bar # 235561)

CENTER FOR BIOLOGICAL DIVERSITY
351 California Street, Suite 600
San Francisco, CA 94104
Telephone: (415) 436-9682
Facsimile: (415) 436-9683
jaugustine@biologicaldiversity.org
cadkinsgiese@biologicaldiversity.org

ATTORNEYS FOR PLAINTIFF

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

CENTER FOR BIOLOGICAL DIVERSITY, Plaintiff, v. U.S. DEPARTMENT OF THE INTERIOR; SALLY JEWELL, in her official capacity as Secretary of the Interior; U.S. FISH AND WILDLIFE SERVICE; DAN ASHE, Director of the U.S. Fish and Wildlife Service, Defendants, CROPLIFE AMERICA, Defendant-Intervenor.	CASE NO. 3:15-cv-658-JCS **STIPULATED SETTLEMENT AND ~~[PROPOSED]~~ ORDER**

Plaintiff Center for Biological Diversity ("the Center"); Sally Jewell, in her official capacity as the Secretary of the Interior, the U.S. Fish and Wildlife Service (the "FWS"), and Dan Ashe, in his official capacity as Director of the Fish and Wildlife Service ("Federal Defendants") (collectively, "the Parties") by and through the undersigned counsel, state as follows:

WHEREAS, under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), the U.S. Environmental Protection Agency ("EPA") is responsible for registering pesticides and ensuring that pesticides do not cause unreasonable adverse effects on the environment, which includes species listed as threatened or endangered ("listed species") under the Federal Endangered Species Act ("ESA");

WHEREAS, pursuant to Section 7 of the ESA, EPA and all federal agencies must, in consultation with and with the assistance of FWS and NMFS, insure that any action authorized, funded, or carried out by such agency is not likely to jeopardize the continued existence of any endangered or threatened species or result in the destruction or adverse modification of their critical habitat;

WHEREAS, over the years, EPA, FWS, and NMFS have used different risk assessment approaches to identify the potential effects of pesticides on threatened and endangered species and were unable to reach a consensus on an approach for assessing the risks to listed species;

WHEREAS, these different approaches to risk assessment have impacted the ability of EPA, FWS and NMFS to complete consultation under the ESA;

WHEREAS, in order to resolve these differences, EPA, FWS, NMFS, and the United States Department of Agriculture ("USDA") asked the National Academy of Sciences ("NAS") to evaluate the differing risk assessment approaches used by these agencies to identify the potential effects of pesticides on threatened and endangered species;

WHEREAS, the NAS responded to that request on April 30, 2013, by issuing a report entitled "Assessing Risks to Endangered and Threatened Species from Pesticides" (the "NAS report");

WHEREAS, the NAS report suggests, *inter alia*, that EPA, FWS, and NMFS take a common approach to assessing the potential effects of pesticides on listed species to facilitate coordination among federal agencies;

WHEREAS, EPA, FWS, and NMFS are now working in close cooperation to evaluate and implement recommendations made by the NAS report;

WHEREAS, FWS, EPA and NMFS are now working collaboratively on the ESA § 7 consultation process for the registration review of certain pesticides under section 3(g) of FIFRA with recommendations provided in the NAS report;

WHEREAS, based on the findings in the NAS report, the work done so far by the agencies to implement recommendations in that report, and the need to align the consultation process with EPA's registration review of pesticides, the Parties agree that when consultation is required, it would be more efficient for EPA and FWS to consult on the potential effects of pesticides on listed species nationwide; the Parties further agree that the agencies still face significant challenges in implementing recommendations of the NAS report and completing such nationwide consultations; accordingly, the Parties acknowledge that the Agencies intend to proceed with nationwide ESA evaluations in a phased, iterative process, taking into account input received and lessons learned from initial efforts to implement NAS recommendations, and maintaining flexibility to pursue processes or methodologies not part of such initial efforts;

WHEREAS, the Center filed a complaint on October 19, 2011 in *Center for Biological Diversity v. U.S. Fish and Wildlife Service et al.*, No. 3:11-cv-5108-JSW (N.D. Cal.) ("CRLF II"), alleging that the FWS and EPA violated Section 7 of the ESA, the ESA's implementing regulations, and the Administrative Procedure Act ("APA"), with regard to the alleged failure to complete consultation as to the effects of 64 pesticide ingredients for which EPA determined in 2009 were likely to affect the California red-legged frog (*Rana draytonii*);

WHEREAS, on November 4, 2013, the Center, FWS and EPA entered into a settlement agreement in CRLF II requiring completion of ESA consultations on the effects of seven (7) chemicals on the California red-legged frog by November 4, 2015 (CRLF II, Dkt. 76). ("November 4, 2013 Agreement");

WHEREAS, on July 28, 2014, the Center, FWS and EPA entered into a stipulation amending the CRLF II November 4, 2013 Agreement to provide that if FWS completes nationwide consultation on five chemicals (carbaryl, chlorpyrifos, diazinon, malathion, and methomyl) by December 31, 2018, FWS shall be deemed to have discharged its obligations under the terms of the original settlement in full (CRLF II, Dkt. 87) ("July 28, 2014 Agreement");

WHEREAS, EPA and FWS are working to complete such nationwide consultations on carbaryl, chlorpyrifos, diazinon, malathion, and methomyl;

WHEREAS, EPA and FWS currently expect to complete nationwide ESA consultations for three of the five pesticides listed above (chlorpyrifos, diazinon, and malathion) by December 31, 2017, and for the remaining two pesticides (carbaryl and methomyl) by December 31, 2018;

WHEREAS, the Center filed a separate complaint on February 12, 2015 in the case at bar, alleging that the FWS has violated Section 7 of the ESA and the APA, with regard to the alleged failure to complete consultation and the effects of atrazine and alachlor on the Delta smelt (*Hypomesus transpacificus*) ("smelt") and 2, 4-D upon the Alameda whipsnake (*Masticophis lateralis euryxanthus*) ("whipsnake") (Dkt. 1);

WHEREAS, based on the findings in the NAS report and the work done so far by the agencies to address recommendations in that report, the Parties now agree that it would be more efficient for FWS to consult on the potential effects that one pesticide at issue in this case (atrazine) as well as three other priority pesticides not at issue in this case (simazine, propazine, and glyphosate) have on listed species on a nationwide basis (if EPA initiates nationwide consultation with FWS on atrazine, simazine, propazine, and glyphosate), instead of completing

consultation on the effects of atrazine and alachlor on only the smelt and 2,4-D on only the whipsnake;

WHEREAS, EPA expects to complete a nationwide evaluation of the effects of four pesticides–atrazine, simazine, propazine and glyphosate–on listed species in connection with registration review under FIFRA and initiate any necessary nationwide ESA consultations for these four pesticides by June 30, 2020 (*Center for Biological Diversity v. Environmental Protection Agency*, No. 3:07-cv-02794-JCS (N.D. Cal.) (Dkt. 154 at 3);

WHEREAS, if EPA initiates nationwide consultation with FWS on atrazine, simazine, propazine, and/or glyphosate, EPA and FWS currently expect to complete such nationwide ESA consultations by December 30, 2022;

WHEREAS, these four pesticides, together with the five pesticides addressed in the CRLF II July 28, 2014 Agreement, constitute a substantial portion of pesticide use in the U.S. by weight annually;

WHEREAS, EPA, FWS, and NMFS are exploring the feasibility of a comprehensive pesticide ESA consultation workplan addressing the registration and registration review of pesticide ingredients under FIFRA;

WHEREAS, the Parties enter into the instant Stipulated Settlement so that FWS will have an opportunity to attempt to complete the potential nationwide consultations described above, while acknowledging that FWS may still be required to complete consultations on the effects of atrazine and alachlor on the smelt and 2,4-D on the whipsnake if it is not able to complete the potential nationwide consultations (although any applicable deadline for such whipsnake and smelt consultation would be determined by the Parties after the mechanism described in paragraph 4, *infra*, is triggered);

WHEREAS, the Center and the Federal Defendants, through their authorized representatives, have reached agreement on the terms of a settlement, which is captured in this Stipulated Settlement, that they consider to be a just, fair, adequate, and equitable resolution of the issues in this case;

WHEREAS, the parties agree that this Stipulated Settlement is in the public interest and is an appropriate way to resolve the remaining disputed issues;

WHEREAS Defendant-Intervenor CropLife America takes no position on this proposed Stipulated Settlement;

NOW, THEREFORE, THE PARTIES STIPULATE AS FOLLOWS:

1. As to the FWS's completion of consultation and delivery to EPA of a final biological opinion on the effects of atrazine and alachlor on the smelt and 2-4,D on the whipsnake, any applicable deadline is hereby suspended to allow the Federal agencies to engage in the potential nationwide consultations described in the above "whereas" clauses.

2. No provision of this Stipulation requires (or shall be construed to require) FWS to conduct the nationwide consultations described above in the "whereas" clauses, and no provision of this Stipulation requires (or shall be construed to require) FWS to complete any such nationwide consultations on the schedule set out in the above "whereas" clauses.

3. While it is not obligated to do so, if EPA initiates and FWS completes nationwide consultation on atrazine, simazine, propazine, and glyphosate on the schedule set out above in the "whereas" clauses, then FWS shall be deemed to have discharged its obligations to complete consultation on the effects of atrazine and alachlor on the smelt and 2,4-D on the whipsnake in full.

4. Alternatively, if

(a) FWS does not complete an EPA-initiated nationwide consultation on atrazine, simazine, propazine and glyphosate on the schedule set out above in the "whereas" clauses;

(b) FWS concludes (based on further review of these issues) that nationwide consultations are no longer appropriate or required; or,

(c) FWS does not complete the interim benchmarks on the estimated schedule described below in Paragraph 5, then:

(1) at the request of either the Center or the Federal Defendants, the Parties shall meet and confer at the earliest available opportunity to discuss whether it is appropriate for FWS to complete the consultations on the effects of atrazine and alachlor on the smelt and 2,4-D on whipsnake described in Paragraph 1, *supra*, and, if so, to discuss an appropriate revised schedule for those consultations; and,

(2) if the Parties are unable to reach agreement on that revised schedule within thirty (30) days of any such meeting and conference, either party may petition the Court to resolve the dispute and set a schedule for the remaining consultations on the effects of atrazine and alachlor on the smelt and 2,4-D on the whipsnake described in Paragraph 1, *supra*.

5. Within 30 days of the Court's approval of this Stipulated Settlement, FWS shall provide the Center (and Intervenor-Defendant) with an estimated schedule, including interim benchmarks, for completing the potential nationwide consultations described above in the "whereas" clauses. That schedule will include estimated dates for FWS's draft biological opinions and FWS's final biological opinions for each of these pesticides, where applicable. The Parties recognize that this schedule will be a good faith estimate as of the date that it is provided, but that the schedule may be subject to change (based on factors including, but not limited to, variations in the estimated dates for data submission, the volume of public comments, and unanticipated legal obligations), and that, as stated above in Paragraph 3, this schedule will not be binding or enforceable by the Court.

6. FWS shall provide the Center (and Intervenor-Defendant) with an update by conference call every four (4) months describing the status of these consultations.

7. Upon entry of this Stipulated Settlement, Plaintiff's complaint shall be dismissed with prejudice.

8. This Stipulation has no precedential value and shall not be used as evidence in litigation or any other court proceeding (other than to enforce this Stipulated Settlement).

9. Within 30 days of the Court's approval of this Stipulated Settlement, the FWS shall post the following on its Pesticide Registrations and ESA Consultations webpage, which is found at http://www.fws.gov/endangered/what-we-do/pesticide-consultation.html : (i) a summary of the principal terms of this Stipulated Settlement, including the schedule discussed in the "whereas" clauses; (ii) a hyperlink to the full text of the Stipulated Settlement; and (iii) a hyperlink to the EPA's webpage covering the stipulated injunction entered in *Center for Biological Diversity v. EPA*, 07-2794 (N.D. Cal., May 17, 2010) (Dkt. 121) ("Order Approving Stipulated Injunction and Order"), which is found at: http://www.epa.gov/endangered-species/original-2010-court-order-cbd-v-epa.

10. The Parties reserve the right to seek to have this Court modify this Stipulated Settlement because of the FWS's ongoing actions to comply with the ESA, to meet the requirements of other federal agencies or departments, or to contend with other circumstances not presently anticipated, including completion of FWS's, NMFS's, and EPA's comprehensive ESA pesticide consultation workplan discussed above in the "whereas" clauses. The Court will consider such future requests as it deems appropriate.

11. In the event of a disagreement between the Parties concerning the interpretation or performance of any aspect of this Stipulated Settlement, the dissatisfied Party shall provide

the other Party with written notice of the dispute and a request for negotiations. The Parties shall confer in order to attempt to resolve the dispute within 14 days after receipt of the notice, or such time thereafter as is mutually agreed upon. If the Parties are unable to resolve the dispute within 21 days after receipt of the notice, or such time thereafter as is mutually agreed upon, then any Party may petition the Court to resolve the dispute.

12. The Federal Defendants agree that Plaintiff is entitled to reimbursement of reasonable attorneys' fees and costs. Federal Defendants and Plaintiff agree to attempt to resolve Plaintiff's claim for fees and costs for all claims in this action expeditiously, without the need for Court intervention. The Parties recognize that Federal Defendants have not waived any defense to and preserve their right to challenge the reasonableness of the amount of attorneys' fees and costs requested by Plaintiff in the event that Plaintiff and Federal Defendants are unable to resolve Plaintiff's claim for fees and costs. The Parties further recognize that Plaintiff reserves the right to seek additional fees and costs incurred arising from a need to enforce or defend against efforts to modify this Stipulated Settlement, to litigate a reasonable award of attorneys' fees and costs, or for any other unforeseen continuation of this action.

13. If the Federal Defendants and Plaintiff cannot agree on the amount of such fees within 60 days of the Court approving this Stipulated Settlement, Plaintiff shall file a motion for attorneys' fees and costs with the Court in this matter. This 60 day period shall supersede the 14 day time period otherwise applicable pursuant to Federal Rules of Civil Procedure Section 54(d)(2)(B) and the court order approving the Stipulated Settlement will accordingly operate as an enlargement of time pursuant to Federal Rules of Civil Procedure Section 6(b)(1) for Plaintiffs to file a fee motion.

14. It is the expectation and understanding of the Parties that if EPA cancels the remaining pesticide registrations containing any of the active ingredients listed in Paragraph 1, FWS shall not be required to complete consultation with regard to that active ingredient.

15. It is furthermore the expectation and understanding of the Parties that if EPA cancels the remaining pesticide registrations containing any of the active ingredients listed in Paragraph 3, FWS shall be deemed to have discharged its consultation commitments for the purposes of Paragraph 3 with regard to that active ingredient.

16. No provision of this Stipulated Settlement shall be interpreted as or constitute a commitment or requirement that the Federal Defendants take action in contravention of the ESA, the APA, or any other law or regulation, either substantive or procedural. Nothing in this Stipulated Settlement shall be construed to limit or modify the discretion accorded to the Federal Defendants by the ESA, the APA, or general principles of administrative law with respect to the procedures to be followed in conducting the ESA consultation described above, or as to the substance of any such determinations.

17. Nothing in this Stipulated Settlement shall bar the Federal Defendants from acting on any matters covered herein in a time frame earlier than required by this Stipulated Settlement, or from taking additional actions not specified herein if the Federal Defendants determines such actions are appropriate under applicable law.

18. Nothing in this Agreement shall be interpreted as, or shall constitute, a requirement that Federal Defendants are obligated to pay any funds exceeding those available, or take any action in contravention of the Anti-Deficiency Act, 31 U.S.C. § 1341, or any other appropriations law.

19. The Parties agree that this Stipulated Settlement was negotiated in good faith and that entry of this Stipulated Settlement constitutes a settlement of claims that were vigorously contested, denied, and disputed by the Parties. By entering into this Stipulated Settlement, the Parties do not waive any claim or defense.

20. The undersigned representatives of each Party certify that they are fully authorized by the Party (or Parties) they represent to agree to the terms and conditions of this Stipulated Settlement and do hereby agree to the terms herein.

21. This Stipulated Settlement does not constitute an admission or evidence of any fact, wrongdoing, misconduct, or liability on the part of the United States, including without limitation, the Federal Defendants, their officers, or any other person affiliated with the FWS, or any interpretation of any applicable provision of law.

22. Plaintiff's sole judicial remedy to address the merits of any final action that may ensue from FWS's performance of its obligations under this Stipulated Settlement is to file a separate lawsuit challenging such final action. The Federal Defendants reserve all defenses to any such suit. Nothing in this Stipulated Settlement alters or affects the standards for review of final agency action, or creates jurisdiction that otherwise would not exist to review agency action.

23. Notwithstanding the dismissal of this action, the Parties have agreed and requested that this Court retain jurisdiction to oversee compliance with the terms of this Stipulated Settlement and to resolve any motions to modify such terms. *See Kokkonen v. Guardian Life Ins. Co. of America*, 511 U.S. 375 (1994).

24. The terms of this Stipulated Settlement constitute the entire agreement of the Parties, and no statement, agreement or understanding, oral or written, which is not contained herein, shall be recognized or enforced.

25. The terms of this Stipulated Settlement shall become effective upon entry of an order by the Court ratifying this Stipulated Settlement.

Respectfully Submitted on this 19th day of February, 2016.

JOHN C. CRUDEN
Assistant Attorney General
SETH M. BARSKY, Chief
S. JAY GOVINDAN,
Assistant Chief

/s/ J. Brett Grosko (by permission)

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Attorneys for Federal Defendants

/s/ Collette Adkins

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jaugustine@biologicaldiversity.org

Attorneys for Plaintiff

PURSUANT TO STIPULATION, IT IS ORDERED that the Settlement Agreement executed by the Parties is hereby incorporated into this Order; and

IT IS FURTHER ORDERED that this Court shall have continuing jurisdiction to enforce this Order and the terms of the Settlement Agreement.

DATED: 2/19/16

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
Judge Joseph C. Spero

Joseph C. Spero
United States Magistrate Judge

Message

From: Cathy Tortorici - NOAA Federal [cathy.tortorici@noaa.gov]
Sent: 8/16/2017 6:27:07 PM
To: Shultz, Gina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userd6a2f351]; Craig Aubrey [craig_aubrey@fws.gov]; Patrice Ashfield [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user1f5a6e17]; Dumas, Richard [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=082146a785ef4acd8bad309466dd313a-Richard P. Dumas]; Echeverria, Marietta [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=36c56b7169144626bd6aadea25992d4e-Marietta Echeverria]; Villanueva, Philip [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93adaf07438a402faa959bb6d04e7d86-Villanueva, Phillip]; Anderson, Brian [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce7d6e5ad2e94b3f8f5ac4d839a6c268-Brian Anderson]; Kunickis, Sheryl - OSEC [sheryl.kunickis@osec.usda.gov]; Perry, Tracy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ffd9b082a6484fe8a70cade93a68466c-Tracy L Perry]; cathy.tortorici@noaa.gov [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1bdaaff0c14a4264abc82f1468af694d-cathy.tortorici@noaa.gov]; Pease, Anita [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dbbef4b4951144499885d4cdf88d46d0-Anita Pease]
Subject: Usage data documents - again
Attachments: Consideration of Pesticide Usage Information 10-3-2016.docx; NMFS GfK request_OPP_response2.docx

--
Cathy Tortorici
Chief, ESA Interagency Cooperation Division
Office of Protected Resources
NOAA's National Marine Fisheries Service
1315 East-West Highway
Silver Spring, MD 20910
(w) 301.427.8495
(c) 301.602.2193
cathy.tortorici@noaa.gov

Message

From: Shultz, Gina [gina_shultz@fws.gov]
Sent: 5/11/2017 11:04:27 PM
To: Kunickis, Sheryl [Sheryl.Kunickis@osec.usda.gov]; Pease, Anita [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dbbef4b4951144499885d4cdf88d46d0-Anita Pease]; Echeverria, Marietta [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=36c56b7169144626bd6aadea25992d4e-Marietta Echeverria]; cathy.tortorici@noaa.gov [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1bdaaff0c14a4264abc82f1468af694d-cathy.tortorici@noaa.gov]; Craig Aubrey [craig_aubrey@fws.gov]; Patrice Ashfield [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user1f5a6e17]; Miller, Kayla M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=useraf8116f4]
Subject: FWS Draft Consultation History
Attachments: FWS Consultation History Draft (5-11-17).docx

I uploaded it to the sharepoint site (also attached).

Gina Shultz
Deputy Assistant Director, Ecological Services
U.S. Fish and Wildlife Service
MS: ES
5275 Leesburg Pike
Falls Church, VA 22041-3803
703-358-1985

Appointment

From: cathy.tortorici@noaa.gov [cathy.tortorici@noaa.gov]
Sent: 9/5/2018 9:26:04 PM
To: Sims, Diann [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7ca5706c9da345c5af43f0899cf3a8df-Diann Sims]; Patrice Ashfield [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user1f5a6e17]; Perry, Tracy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ffd9b082a6484fe8a70cade93a68466c-Tracy L Perry]; Miller, Wynne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8267862f7fea4782aec32ea5fec8c19c-wymiller]; NMFS - HQ - PR5 Conference Line [noaa.gov_3333343738353730 2d343932@resource.calendar.google.com]; Anderson, Brian [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce7d6e5ad2e94b3f8f5ac4d839a6c268-Brian Anderson]; craig_aubrey@fws.gov; ashley_stilson@fws.gov; Paula.JonesYates@noaa.gov [paula.jonesyates@noaa.gov]; Echeverria, Marietta [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=36c56b7169144626bd6aadea25992d4e-Marietta Echeverria]; sheryl.kunickis@osec.usda.gov; Guilaran, Yu-Ting [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a698774e93e34a2b9181d4b3032b8a32-ytguilar]; lois_wellman@fws.gov; Shultz, Gina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userd6a2f351]

Subject: Updated invitation: ESA/Pesticide Sr. Mgrs Call @ Thu Sep 6, 2018 8am - 9am (EDT) (echeverria.marietta@epa.gov)
Attachments: invite.ics
Location: NMFS - HQ - PR5 Conference Line

Start: 9/6/2018 12:00:00 PM
End: 9/6/2018 1:00:00 PM
Show Time As: Tentative

Recurrence: (none)

This event has been changed.

more details »

ESA/Pesticide Sr. Mgrs Call

When Thu Sep 6, 2018 8am – 9am Eastern Time - New York

Where NMFS - HQ - PR5 Conference Line (map)

Calendar echeverria.marietta@epa.gov

Who
- cathy.tortorici@noaa.gov - organizer
- Paula.JonesYates@noaa.gov - creator
- sims.diann@epa.gov
- patrice_ashfield@fws.gov
- perry.tracy@epa.gov
- miller.wynne@epa.gov
- anderson.brian@epa.gov
- craig_aubrey@fws.gov
- ashley_stilson@fws.gov
- echeverria.marietta@epa.gov
- sheryl.kunickis@osec.usda.gov

- guilaran.yu-ting@epa.gov
- lois_wellman@fws.gov
- Gina_Shultz@fws.gov

Changed: Agenda items -

First 15 minutes -

- Getting useage data on bromoxynil and prometryn for the NMFS BiOp
- Status of the Florida useage pilot
- The EPA RPA/RPM document
- FWS conversation with Registrants on getting useage data?
- Report to Congress (EFED)
- Letter exchange for admin record (PRD)
- Expectations on reporting out from usage meetings? (EFED)

Last 45 minutes -

- malathion consultation timeline/litigation (Just FWS/EPA)

Participant call-in details:

Personal Matters / Ex. 6

==========

AGENDA ITEMS
- Malathion consultation timeline

Going? **Yes** - **Maybe** - **No** more options »

Appointment

From: cathy.tortorici@noaa.gov [cathy.tortorici@noaa.gov]
To: sims.diann@epa.gov; patrice_ashfield@fws.gov; perry.tracy@epa.gov; miller.wynne@epa.gov; NMFS - HQ - PR5 Conference Line [noaa.gov_3333437383537302d343932@resource.calendar.google.com]; anderson.brian@epa.gov; craig_aubrey@fws.gov; ashley_stilson@fws.gov; Paula.JonesYates@noaa.gov [paula.jonesyates@noaa.gov]; echeverria.marietta@epa.gov; sheryl.kunickis@osec.usda.gov; guilaran.yu-ting@epa.gov; lois_wellman@fws.gov; Gina_Shultz@fws.gov [gina_shultz@fws.gov]

Subject: ESA/Pesticide Sr. Mgrs Call
Location: NMFS - HQ - PR5 Conference Line

Start: 9/6/2018 12:00:00 PM
End: 9/6/2018 1:00:00 PM
Show Time As: Tentative

Recurrence: (none)

Agenda items -

First 15 minutes -

- Getting useage data on bromoxynil and prometryn for the NMFS BiOp
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Participant call-in details:

Personal Matters / Ex. 6

==========

AGENDA ITEMS
- Malathion consultation timeline

-::~:~::~::~:~::-
Please do not edit this section of the description.

View your event at
https://www.google.com/calendar/event?action=VIEW&eid=M2N1cmFzOWc2ZjczMXVobGV2MjhmMm5rb2RfMjAxODA5MDZUMTIwMDAwWiBlY2hldmVycmlhLm1hcmlldHRhQGVwYS5nb3Y&tok=MjQjY2F0aHkudG9ydG9yaWNpQG5vYWEuZ292OTU0Y2E5MmZlNzhjNzI4OTdkZWRmMDRjM2ZiYTFmMjY0NzRiNjFiNQ&ctz=America%2FNew_York&hl=en&es=0.
-::~:~::~::~:~::-

Message

From: Anderson, Brian [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CE7D6E5AD2E94B3F8F5AC4D839A6C268-BRIAN ANDERSON]
Sent: 9/5/2018 9:22:20 PM
To: Shultz, Gina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userd6a2f351]; cathy.tortorici@noaa.gov [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1bdaaff0c14a4264abc82f1468af694d-cathy.tortorici@noaa.gov]
CC: Patrice Ashfield [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user1f5a6e17]; Guilaran, Yu-Ting [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a698774e93e34a2b9181d4b3032b8a32-ytguilar]; Kunickis, Sheryl [sheryl.kunickis@osec.usda.gov]; Miller, Wynne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8267862f7fea4782aec32ea5fec8c19c-wymiller]; Sims, Diann [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7ca5706c9da345c5af43f0899cf3a8df-Diann Sims]; Craig Aubrey [craig_aubrey@fws.gov]; Perry, Tracy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ffd9b082a6484fe8a70cade93a68466c-Tracy L Perry]; Lois Wellman [lois_wellman@fws.gov]; Ashley Stilson [ashley_stilson@fws.gov]; Echeverria, Marietta [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=36c56b7169144626bd6aadea25992d4e-Marietta Echeverria]
Subject: RE: [EXTERNAL] Updated invitation: ESA/Pesticide Sr. Mgrs Call @ Thu Sep 6, 2018 8am - 9am (EDT) (gina_shultz@fws.gov)

A few quick things.

- Report to Congress (EFED)
- Letter exchange for admin record (PRD)
- Expectations on reporting out from usage meetings? (EFED)

From: Shultz, Gina [mailto:gina_shultz@fws.gov]
Sent: Wednesday, September 05, 2018 2:22 PM
To: cathy.tortorici@noaa.gov
Cc: Patrice Ashfield <patrice_ashfield@fws.gov>; Guilaran, Yu-Ting <Guilaran.Yu-Ting@epa.gov>; Kunickis, Sheryl <sheryl.kunickis@osec.usda.gov>; Miller, Wynne <Miller.Wynne@epa.gov>; Sims, Diann <Sims.Diann@epa.gov>; Craig Aubrey <craig_aubrey@fws.gov>; Anderson, Brian <Anderson.Brian@epa.gov>; Perry, Tracy <Perry.Tracy@epa.gov>; Lois Wellman <lois_wellman@fws.gov>; Ashley Stilson <ashley_stilson@fws.gov>; Echeverria, Marietta <Echeverria.Marietta@epa.gov>
Subject: Re: [EXTERNAL] Updated invitation: ESA/Pesticide Sr. Mgrs Call @ Thu Sep 6, 2018 8am - 9am (EDT) (gina_shultz@fws.gov)

Please add malathion consultation timeline. thank you, Gina

Gina Shultz
Deputy Assistant Director, Ecological Services
U.S. Fish and Wildlife Service
MS: ES
5275 Leesburg Pike
Falls Church, VA 22041-3803
703-358-1985

On Wed, Sep 5, 2018 at 1:55 PM, <cathy.tortorici@noaa.gov> wrote:

This event has been changed.

more details »

ESA/Pesticide Sr. Mgrs Call

Changed:
Agenda items -

- Getting useage data on bromoxynil and prometryn for the NMFS BiOp
- Status of the Florida useage pilot
- The EPA RPA/RPM document
- FWS conversation with Registrants on getting useage data?

Personal Matters / Ex. 6

==========

AGENDA ITEMS
- Malathion consultation timeline

When Thu Sep 6, 2018 8am – 9am Eastern Time - New York

Where NMFS - HQ - PR5 Conference Line (map)

Calendar gina_shultz@fws.gov

Who
- cathy.tortorici@noaa.gov - organizer
- Paula.JonesYates@noaa.gov - creator
- patrice_ashfield@fws.gov
- guilaran.yu-ting@epa.gov
- sheryl.kunickis@osec.usda.gov
- miller.wynne@epa.gov
- sims.diann@epa.gov
- craig_aubrey@fws.gov
- anderson.brian@epa.gov
- perry.tracy@epa.gov
- lois_wellman@fws.gov
- Gina_Shultz@fws.gov
- ashley_stilson@fws.gov
- echeverria.marietta@epa.gov

Going? **Yes** - **Maybe** - **No** more options »

Message

From: Villanueva, Philip [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=93ADAF07438A402FAA959BB6D04E7D86-VILLANUEVA, PHILLIP]
Sent: 4/27/2017 2:19:28 PM
To: Gina_Shultz@fws.gov [gina_shultz@fws.gov]; sheryl.kunickis@osec.usda.gov; Guilaran, Yu-Ting [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a698774e93e34a2b9181d4b3032b8a32-ytguilar]; Patrice Ashfield [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user1f5a6e17]; cathy.tortorici@noaa.gov [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1bdaaff0c14a4264abc82f1468af694d-cathy.tortorici@noaa.gov]; Pease, Anita [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dbbef4b4951144499885d4cdf88d46d0-Anita Pease]; Echeverria, Marietta [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=36c56b7169144626bd6aadea25992d4e-Marietta Echeverria]; kayla_miller@fws.gov; Dumas, Richard [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=082146a785ef4acd8bad309466dd313a-Richard P. Dumas]; Perry, Tracy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ffd9b082a6484fe8a70cade93a68466c-Tracy L Perry]
Subject: RE: Invitation: ESA/Pesticide Senior Managers @ Weekly from 8am to 9am on Thursday (EDT) (villanueva.philip@epa.gov)
Attachments: Wiley Rein letter comments comparison.xlsx

All,

Please find attached a chart with the summarized comments in the front portion of three chemical-specific analyses attached to the Wiley Rein letter. They are pretty consistent across chemicals.

Phil

****

Philip Villanueva, Chief
Environmental Information Support Branch
Environmental Fate and Effects Division
Office of Pesticide Programs, U.S. EPA
1200 Pennsylvania Avenue, NW (7507P)
Washington, DC 20460
phone: (703) 308-8665
mobile: (571) 319-3318
fax: (703) 305-0204
e-mail: villanueva.philip@epa.gov
****

Visit OPP at www.epa.gov/pesticides/

-----Original Appointment-----
From: Gina_Shultz@fws.gov [mailto:gina_shultz@fws.gov]
Sent: Thursday, March 09, 2017 9:23 AM
To: Gina_Shultz@fws.gov; sheryl.kunickis@osec.usda.gov; Guilaran, Yu-Ting; Patrice Ashfield; cathy.tortorici@noaa.gov; Pease, Anita; Echeverria, Marietta; kayla_miller@fws.gov; Dumas, Richard; Villanueva, Philip; Perry, Tracy
Subject: Invitation: ESA/Pesticide Senior Managers @ Weekly from 8am to 9am on Thursday (EDT) (villanueva.philip@epa.gov)
When: Thursday, April 27, 2017 8:00 AM-9:00 AM America/New_York.
Where: **Personal Matters / Ex. 6**

more details »

ESA/Pesticide Senior Managers

When Weekly from 8am to 9am on Thursday Eastern Time

Where **Personal Matters / Ex. 6**

Video call https://plus.google.com/hangouts/_/doi.gov/gina-shultz

Calendar villanueva.philip@epa.gov

Who
- Gina_Shultz@fws.gov - organizer
- lois_wellman@fws.gov - creator
- sheryl.kunickis@osec.usda.gov
- guilaran.yu-ting@epa.gov
- patrice_ashfield@fws.gov
- cathy.tortorici@noaa.gov
- pease.anita@epa.gov
- echeverria.marietta@epa.gov
- kayla_miller@fws.gov
- dumas.richard@epa.gov
- villanueva.philip@epa.gov
- perry.tracy@epa.gov

Going? All events in this series: **Yes** - **Maybe** - **No** more options »

Message

From: Miller, Kayla [kayla_miller@fws.gov]
Sent: 5/18/2017 1:15:08 PM
To: Echeverria, Marietta [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=36c56b7169144626bd6aadea25992d4e-Marietta Echeverria]; Pease, Anita [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dbbef4b4951144499885d4cdf88d46d0-Anita Pease]; Villanueva, Philip [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93adaf07438a402faa959bb6d04e7d86-Villanueva, Phillip]; Dumas, Richard [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=082146a785ef4acd8bad309466dd313a-Richard P. Dumas]; Kunickis, Sheryl - OSEC [sheryl.kunickis@osec.usda.gov]; cathy.tortorici@noaa.gov [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1bdaaff0c14a4264abc82f1468af694d-cathy.tortorici@noaa.gov]; Perry, Tracy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ffd9b082a6484fe8a70cade93a68466c-Tracy L Perry]
CC: Shultz, Gina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userd6a2f351]; Craig Aubrey [craig_aubrey@fws.gov]; Patrice Ashfield [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user1f5a6e17]
Subject: FWS Pest Consultation 101 Presentation to Politicals
Attachments: DOI Politicals Presentation National Pesticide Consultation.pptx

Hello All,

There is now only one chlorpyrifos arachnids scorecard on Sharepoint. Attached is the presentation Gina gave on Monday to the FWS political team.

Thanks,
Kayla

--
Knauss Fellow 2017-2018
Special Assistant to the Deputy Assistant Director, Ecological Services
U.S. Fish and Wildlife Service

5275 Leesburg Pike
Falls Church, VA 22041-3803
703-358-1898

Message

From: Ashfield, Patrice [patrice_ashfield@fws.gov]
Sent: 8/22/2018 8:57:47 PM
To: Echeverria, Marietta [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=36c56b7169144626bd6aadea25992d4e-Marietta Echeverria]; Miller, Wynne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8267862f7fea4782aec32ea5fec8c19c-wymiller]; Anderson, Brian [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce7d6e5ad2e94b3f8f5ac4d839a6c268-Brian Anderson]
CC: Shultz, Gina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userd6a2f351]
Subject: Draft Timeline
Attachments: Mala Draft consult timeline.xlsx; Draft timeline for malathion BO_Aug 2018_pma.docx

Dear Folks-
Attached is our draft timeline for the malathion consultation. Talk to you tomorrow!
pma

Patrice M. Ashfield
Branch Chief for National Pesticide Consultations
Headquarters, Fish and Wildlife Service
5275 Leesburg Pike, MS:ES
Falls Church, VA 22041
(703) 358-2478 office

Message

From: Aubrey, Craig [craig_aubrey@fws.gov]
Sent: 8/16/2018 3:17:21 PM
To: Echeverria, Marietta [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=36c56b7169144626bd6aadea25992d4e-Marietta Echeverria]; Shultz, Gina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userd6a2f351]; Patrice Ashfield [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user1f5a6e17]
Subject: White paper for discussion this pm
Attachments: FWS_EPA_ActionArea_Issue 08.16.2018_FWS comments v2.docx

Marietta, pls see attached for this pm. talk to u at 1.

Craig

Craig W. Aubrey
Chief, Division of Environmental Review
Ecological Services Program
U.S. Fish and Wildlife Service Headquarters
Ecological Services, MS: ES
5275 Leesburg Pike
Falls Church, VA 22041-3803
703-358-2171 (general)
703-358-2442 (direct)

Message

From: Cathy Tortorici - NOAA Federal [cathy.tortorici@noaa.gov]
Sent: 4/13/2017 9:03:07 PM
To: Gina Shultz [gina_shultz@fws.gov]; Patrice Ashfield [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user1f5a6e17]; Pease, Anita [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dbbef4b4951144499885d4cdf88d46d0-Anita Pease]; Kunickis, Sheryl [Sheryl.Kunickis@osec.usda.gov]; Echeverria, Marietta [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=36c56b7169144626bd6aadea25992d4e-Marietta Echeverria]; Villanueva, Philip [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93adaf07438a402faa959bb6d04e7d86-Villanueva, Phillip]
Subject: Fwd: Letters to Secretary Ross, Secretary Zinke, and Administrator Pruitt from Dow AgroSciences LLC, ADAMA, and FMC Corporation
Attachments: Letters to Secretary Ross, Secretary Zinke, and Administrator Pruitt 4-13-17.pdf

Just in case you missed this letter.

--
Cathy Tortorici
Chief, ESA Interagency Cooperation Division
Office of Protected Resources
NOAA's National Marine Fisheries Service
1315 East-West Highway
Silver Spring, MD 20910
(w) 301.427.8495
(c) 301.602.2193
cathy.tortorici@noaa.gov

Wiley Rein LLP

1776 K STREET NW
WASHINGTON, DC 20006
PHONE 202.719.7000

www.wileyrein.com

April 13, 2017

David B. Weinberg
202.719.7102
DWeinberg@wileyrein.com

The Honorable Wilbur Ross
Secretary
U.S. Department of Commerce
1401 Constitution Avenue, NW
Washington, DC 20230

Re: "Final" Chlorpyrifos, Diazinon, and Malathion Biological Evaluations Sent by EPA to National Marine Fisheries Service on January 18, 2017

Dear Secretary Ross:

We are writing on behalf of our clients Dow AgroSciences, LLC ("DAS"), Makhteshim Agan of North America, Inc., d/b/a ADAMA ("ADAMA"), and FMC Corporation ("FMC") (together, the "OP Registrants"), to request that you (1) instruct the Acting Assistant Administrator for the National Marine Fisheries Service ("NMFS") to return to the U.S. Environmental Protection Agency ("EPA") three Biological Evaluations ("BEs") that EPA transmitted to NMFS on January 18, 2017; (2) direct that any effort to prepare biological opinions based on them be set aside; and (3) as soon as is reasonably possible (as explained further below), direct legal counsel representing NMFS in *NW Coalition for Alternatives to Pesticides, et al. v. National Marine Fisheries Service*, No. 07-cv-01791 (W.D. Wash.) ("*NCAP v. NMFS*"), to file a motion requesting modification of the existing stipulated settlement agreement to extend the deadline for NMFS to complete nationwide organophosphate ("OP") biological opinions.

Our clients and their affiliates hold EPA registrations for products containing one or more of the OP pesticide active ingredients that are the subject of the BEs (chlorpyrifos, diazinon, and malathion). The BEs are documents from EPA required by the "Interim Approaches" adopted during the Obama Administration in an effort to resolve controversies regarding the relationship between pesticide registration activities under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") and activities of EPA and the Departments of Commerce and the Interior under the Endangered Species Act ("ESA").[1]

[1] Interim Approaches for National-Level Pesticide Endangered Species Act Assessments Based on the Recommendations of the National Academy of Sciences April 2013 Report, *available at* https://www.epa.gov/sites/production/files/2015-07/documents/interagency.pdf.

Our clients believe that the Interim Approaches are fundamentally flawed and should be set aside. Drafts of the BEs were released for public review in April, 2016. Substantial comments submitted on those drafts explained the reasons for our clients' view and demonstrated the many flaws in the draft documents.

When EPA sent final versions of the BEs to NMFS, the Agency conceded that it had not responded to most of the comments it had received. This is confirmed in the three reports from expert consultants to our clients that are enclosed with this letter. Those comments also demonstrate that EPA has not even correctly applied in the BEs the processes described as the Interim Approaches.

We will not belabor here the matters addressed in the enclosed reports. But representative examples of the BEs' flaws include the following:

- A major lack of transparency necessary for evaluation and reproduction of results.
- Inclusion of proposed and candidate species that are not afforded protection under ESA.
- Many studies selected by EPA as sources of information on effects and exposure were not evaluated for data quality and relevance. When evaluated, many evaluations did not follow EPA's own study quality criteria. In addition, many scientifically valid, registrant-submitted studies were not evaluated by the Agency, with no explanation. This is not justified and is contrary to EPA's own guidance and the recommendations made by the National Academy of Sciences.
- Effects determinations were made assuming that product may be applied anywhere in the United States, without consideration of distinctions between use patterns, timing of applications, locations of use, and presence of listed species and critical habitats.
- Compounding of conservatism in the assessment of exposure, resulting in unrealistically high and sometimes physically impossible estimates.

- Failure to consider appropriate lines of evidence, as recommended by the National Academy of Sciences, in order to determine the likelihood of an effect occurring.

EPA sought to excuse its failure to properly revise the drafts or otherwise respond to comments by asserting that the revisions were precluded by a legal obligation to complete biological opinions based upon the BEs by December 31, 2017.[2] That position is incorrect. EPA is not bound by any such obligation.

EPA presumably based its assertion on stipulations entered in court cases by NMFS and the U.S. Fish and Wildlife Service ("FWS"). The one of those stipulations to which NMFS was a party did commit NMFS to complete a nationwide OP biological opinion by December 31, 2017. Stipulation and Order to Amend the Stipulated Settlement Agreement Affirmed by this Court on August 1, 2008, *NCAP v. NMFS* (W.D. Wash., May 21, 2014), Dkt. No. 50, at 6.[3] But a party to a settlement agreement may request, by motion, that the court modify the settlement agreement for any "reason that justifies relief." Fed. R. Civ. P. 60. Thus, rather than issue flawed BEs, EPA could have asked NMFS to seek to modify the *NCAP v. NMFS* settlement agreement deadline so EPA could adequately fulfill its own statutory obligations.

---

[2] Office of Chemical Safety and Pollution Prevention's Response to Comments on the Draft Biological Evaluations for Chlorpyrifos, Diazinon, and Malathion, at 2 (Jan. 17, 2017), *available at* https://www3.epa.gov/pesticides/nas/final/response-to-comments.pdf. In failing to "explain or support several assumptions critical to its conclusions," EPA violated the Fourth Circuit Court of Appeals' direction that an agency acting to implement the ESA must explain its analysis "with sufficient clarity" to allow stakeholders to determine whether the analysis is "the product of reasoned decisionmaking." *Dow AgroSciences LLC v. Nat'l Marine Fisheries Serv.*, 707 F.3d 462, 464, 475 (4th Cir. 2013). For example, EPA relied on several data sets that it does not dispute are incomplete and/or inaccessible. But it never "cogently explain[ed] why." *Id.* at 473.

[3] The FWS entered into an analogous stipulation in *Center for Biological Diversity v. U.S. Fish and Wildlife Service et al.* *See* Stipulation Amending Original Stipulated Settlement and Order, No. 11-cv-5108 (N.D. Cal. July 28, 2014), Dkt. No. 87 ("Amended Stipulated Settlement"). But that stipulation expressly states that FWS "is not obligated to" complete OP consultations by December 31, 2017, and it provides that if there were to be a delay the parties would meet and confer to discuss appropriate actions and, if necessary, petition the Court to resolve any dispute. Amended Stipulated Settlement at 4-5. We recently have written to Secretary Zinke about the need to address the issues raised by that settlement.

We recently have written to EPA Administrator Pruitt asking that he withdraw from NMFS the three BEs at issue. However, we urge that you not await that action. Instead, our clients respectfully request that you promptly return the BEs to EPA and direct that any effort to prepare biological opinions based on them be set aside. Our clients similarly request that once you, FWS, EPA, and presumably the U.S. Department of Agriculture (which was a party to the development of the "Interim Approaches") have determined how the new Administration is going to address the "Interim Approaches" and, more broadly, the issue of FIFRA-ESA integration, you direct the legal counsel representing NMFS to file a motion to modify the *NCAP v. NMFS* settlement agreement to extend the deadline for nationwide OP biological opinions and take any other appropriate action, and provide EPA with additional time to prepare the BEs.

Thank you for your prompt attention to these requests.

Sincerely,

David B. Weinberg

Counsel to Dow AgroSciences, LLC; Makhteshim Agan of North America, Inc., d/b/a "ADAMA"; and FMC Corporation

Enclosures

cc (without attachments except as noted):

The Honorable Scott Pruitt, Administrator of the United States Environmental Protection Agency
The Honorable Ryan Zinke, Secretary of the United States Department of the Interior
The Honorable Michael Young, Acting Deputy Secretary of the United States Department of Agriculture
The Honorable Jim Kurth, Acting Director of the Fish and Wildlife Service (with attachments)
The Honorable Samuel D. Rauch, III, Acting Assistant Administrator for the National Marine Fisheries Service
The Honorable John Barrasso, Chairman, Senate EPW Committee
The Honorable Tom Carper, Ranking Member, Senate EPW Committee
The Honorable Rob Bishop, Chairman, House Committee on Natural Resources
The Honorable Raul Grijalva, Ranking Member, House Committee on Natural Resources
The Honorable Pat Roberts, Chairman, Senate Committee on Agriculture, Nutrition and Forestry
The Honorable Debbie Stabenow, Ranking Member, Senate Committee on Agriculture, Nutrition and Forestry
The Honorable Michael Conaway, Chairman, House Committee on Agriculture
The Honorable Collin Peterson, Ranking Member, House Committee on Agriculture
Dr. Sheryl H. Kunickis, Director, Office of Pest Management Policy, United States Department of Agriculture
Mr. Ray Starling, Special Assistant to the President for Agriculture, Trade and Food Assistance (with attachments)
Mr. Richard Keigwin, EPA OPP (with attachments)
Mr. George Oliver, DAS
Ms. Laura Phelps, ADAMA
Mr. Paul Whatling, FMC

Wiley Rein LLP

1776 K STREET NW
WASHINGTON, DC 20006
PHONE 202.719.7000

www.wileyrein.com

April 13, 2017

David B. Weinberg
202.719.7102
DWeinberg@wileyrein.com

The Honorable Ryan Zinke
Secretary
U.S. Department of the Interior
1849 C Street, NW
Washington, DC 20240

Re: "Final" Chlorpyrifos, Diazinon, and Malathion Biological Evaluations Sent by EPA to Fish and Wildlife Service on January 18, 2017

Dear Secretary Zinke:

We are writing on behalf of our clients Dow AgroSciences, LLC ("DAS"), Makhteshim Agan of North America, Inc., d/b/a ADAMA ("ADAMA"), and FMC Corporation ("FMC") (together, the "OP Registrants"), to request that you (1) instruct the Acting Director of the Fish and Wildlife Service ("FWS") to return to the U.S. Environmental Protection Agency ("EPA") three Biological Evaluations ("BEs") that EPA transmitted to FWS on January 18, 2017; (2) direct that any effort to prepare biological opinions based on them be set aside; and (3) direct legal counsel representing FWS in *Center for Biological Diversity v. U.S. Fish and Wildlife Service et al.*, No. 11-cv-5108 (N.D. Cal.) ("*CBD v. FWS*"), to meet and confer on a timely basis with counsel for the other parties to that case, as required by Paragraph 4(c)(1) of the Stipulation Amending Original Stipulated Settlement and Order approved by the Court on July 28, 2014 (the "Stipulated Settlement"), to discuss further activity in that case. *See* Stipulated Settlement, *CBD v. FWS*, Dkt. No. 87.

Our clients and their affiliates hold EPA registrations for products containing one or more of the organophosphate ("OP") pesticide active ingredients that are the subject of the BEs (chlorpyrifos, diazinon, and malathion). The BEs are documents from EPA required by the "Interim Approaches" adopted during the Obama Administration in an effort to resolve controversies regarding the relationship between pesticide registration activities under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") and activities of EPA and the

Departments of the Interior and Commerce under the Endangered Species Act ("ESA").[1]

Our clients believe that the Interim Approaches are fundamentally flawed and should be set aside. Drafts of the BEs were released for public review in April, 2016, and substantial comments submitted on those drafts explained the reasons for our clients' view and demonstrated the many flaws in the draft documents.

When EPA sent final versions of the BEs to FWS, the Agency conceded that it had not responded to most of the comments it had received. This is confirmed in the three reports from expert consultants to our clients that are enclosed with this letter. Those comments also demonstrate that EPA has not even correctly applied in the BEs the processes described as the Interim Approaches.

We will not belabor here the matters addressed in the enclosed reports. But some representative examples of the BEs' flaws include the following:

- A major lack of transparency necessary for evaluation and reproduction of results.
- Inclusion of proposed and candidate species that are not afforded protection under ESA.
- Many studies selected by EPA as sources of information on effects and exposure were not evaluated for data quality and relevance. When evaluated, many evaluations did not follow EPA's own study quality criteria. In addition, many scientifically valid, registrant-submitted studies were not evaluated by the Agency, with no explanation. This is not justified and is contrary to EPA's own guidance and the recommendations made by the National Academy of Sciences.
- Effects determinations were made assuming that product may be applied anywhere in the United States, without consideration of

[1] Interim Approaches for National-Level Pesticide Endangered Species Act Assessments Based on the Recommendations of the National Academy of Sciences April 2013 Report, *available at* https://www.epa.gov/sites/production/files/2015-07/documents/interagency.pdf.

distinctions between use patterns, timing of applications, locations of use, and presence of listed species and critical habitats.

- Compounding of conservatism in the assessment of exposure, resulting in unrealistically high and sometimes physically impossible estimates.

- Failure to consider appropriate lines of evidence, as recommended by the National Academy of Sciences in order to determine the likelihood of an effect occurring.

EPA sought to excuse its failure to properly revise the drafts or otherwise respond to comments by asserting that the revisions were precluded by a legal obligation to complete biological opinions based upon the BEs by December 31, 2017.[2] That position is incorrect. EPA is not bound by any such obligation.

EPA presumably based its assertion on stipulations entered in court cases by FWS and the National Marine Fisheries Service ("NMFS"). The one of those stipulations to which FWS was a party did express an intent to complete a nationwide OP biological opinion by December 31, 2017. *See CBD v. FWS* Stipulated Settlement at 3.[3] But it also expressly stated that FWS "is not obligated to" complete OP consultations by then, and provided that if there were to be a delay

---

[2] Office of Chemical Safety and Pollution Prevention's Response to Comments on the Draft Biological Evaluations for Chlorpyrifos, Diazinon, and Malathion, at 2 (Jan. 17, 2017), *available at* https://www3.epa.gov/pesticides/nas/final/response-to-comments.pdf. In failing to "explain or support several assumptions critical to its conclusions," EPA violated the Fourth Circuit Court of Appeals' direction that an agency acting to implement the ESA must explain its analysis "with sufficient clarity" to allow stakeholders to determine whether the analysis is "the product of reasoned decisionmaking." *Dow AgroSciences LLC v. Nat'l Marine Fisheries Serv.*, 707 F.3d 462, 464, 475 (4th Cir. 2013). For example, EPA relied on several data sets that it does not dispute are incomplete and/or inaccessible. But it never "cogently explain[ed] why." *Id.* at 473.

[3] The National Marine Fisheries Service entered into an analogous stipulation in May 2014 in which it agreed to complete an OP biological opinion by December 31, 2017. *See* Stipulation and Order to Amend the Stipulated Settlement Agreement Affirmed by this Court on August 1, 2008, *NW Coalition for Alternatives to Pesticides, et al. v. Nat'l Marine Fisheries Serv.*, No. 07-cv-01791 (W.D. Wash., May 21, 2014), Dkt. No. 50, at 6.

parties would meet and confer to discuss appropriate actions and, if necessary, petition the Court to resolve any dispute. *Id.* at 4-5.

We recently have written to EPA Administrator Pruitt asking that he withdraw from FWS the three BEs at issue. However, we urge that you not await that action. Instead, our clients respectfully request that you promptly return the BEs to EPA and direct that any effort to prepare biological opinions based on them be set aside. Our clients similarly request that once you, NMFS, EPA, and presumably the U.S. Department of Agriculture (which was a party to development of the "Interim Approaches") have determined how the new Administration is going to address the "Interim Approaches" and, more broadly, the issue of FIFRA-ESA integration, you direct the legal counsel representing FWS in *CBD v. FWS* to meet and confer on a timely basis with counsel for the other parties to that case to discuss appropriate further actions.

Thank you for your prompt attention to these requests.

Sincerely,

David B. Weinberg

Counsel to Dow AgroSciences, LLC; Makhteshim Agan of North America, Inc., d/b/a "ADAMA"; and FMC Corporation

Enclosures

cc (without attachments except as noted):

The Honorable Scott Pruitt, Administrator of the United States Environmental Protection Agency
The Honorable Wilbur Ross, Secretary of the United States Department of Commerce
The Honorable Michael Young, Acting Deputy Secretary of the United States Department of Agriculture
The Honorable Jim Kurth, Acting Director of the Fish and Wildlife Service (with attachments)
The Honorable Samuel D. Rauch, III, Acting Assistant Administrator for the National Marine Fisheries Service
The Honorable John Barrasso, Chairman, Senate EPW Committee
The Honorable Tom Carper, Ranking Member, Senate EPW Committee
The Honorable Rob Bishop, Chairman, House Committee on Natural Resources
The Honorable Raul Grijalva, Ranking Member, House Committee on Natural Resources
The Honorable Pat Roberts, Chairman, Senate Committee on Agriculture, Nutrition and Forestry
The Honorable Debbie Stabenow, Ranking Member, Senate Committee on Agriculture, Nutrition and Forestry
The Honorable Michael Conaway, Chairman, House Committee on Agriculture
The Honorable Collin Peterson, Ranking Member, House Committee on Agriculture
Dr. Sheryl H. Kunickis, Director, Office of Pest Management Policy, United States Department of Agriculture
Mr. Ray Starling, Special Assistant to the President for Agriculture, Trade and Food Assistance (with attachments)
Mr. Richard Keigwin, EPA OPP (with attachments)
Mr. George Oliver, DAS
Ms. Laura Phelps, ADAMA
Mr. Paul Whatling, FMC

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April 13, 2017

David B. Weinberg
202.719.7102
DWeinberg@wileyrein.com

The Honorable Scott Pruitt
Administrator
United States Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Re: "Final" EPA Chlorpyrifos, Diazinon, and Malathion Biological Evaluations Released on January 18, 2017

Dear Mr. Administrator:

We are writing on behalf of our clients Dow AgroSciences, LLC ("DAS"), Makhteshim Agan of North America, Inc., d/b/a ADAMA ("ADAMA"), and FMC Corporation ("FMC") (together, the "OP Registrants"), to request that you withdraw from the Fish and Wildlife Service ("FWS") and National Marine Fisheries Service ("NMFS") (jointly, "the Services") three Biological Evaluations ("BEs") that the Environmental Protection Agency ("EPA") transmitted to them on January 18, 2017.

Our clients and their affiliates hold EPA registrations for products containing one or more of the organophosphate ("OP") pesticide active ingredients that are the subject of the BEs: chlorpyrifos, diazinon, and malathion.

Our clients are unclear about the Administration's intentions related to the ongoing controversy regarding the intersection between pesticide registration activities under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") and activities of EPA and the Services under the Endangered Species Act ("ESA"). We would welcome the opportunity to discuss that issue with you. However, our clients' immediate concern is with the fundamental scientific unsoundness of the OP BEs.

The BEs purportedly were prepared in accordance with the "Interim Approaches" to FIFRA-ESA issues adopted by the Obama Administration in November, 2013.[1] Our clients believe that the Interim Approaches are

[1] Interim Approaches for National-Level Pesticide Endangered Species Act Assessments Based on the Recommendations of the National Academy of Sciences April 2013 Report, *available at* https://www.epa.gov/sites/production/files/2015-07/documents/interagency.pdf.

fundamentally flawed and should be set aside. Each client filed substantial comments on drafts of the BEs that were released for public review in April, 2016. Those comments document our clients' views. Yet EPA conceded in its response to these comments that it did not address most of them in the final versions of the BEs.

Reviews of those "final" BEs, enclosed with this letter, confirm this fact. It also demonstrates that the Agency did not correctly apply processes described in the Interim Approaches. Below are what our clients consider some of the most egregious examples of these shortcomings of the BEs:

- A major lack of transparency necessary for evaluation and reproduction of results.
- Inclusion of proposed and candidate species that are not afforded protection under the ESA.
- Many studies selected by EPA as sources of information on effects and exposure were not evaluated for data quality and relevance. When evaluated, many evaluations did not follow EPA's own study quality criteria. In addition, many scientifically valid, registrant-submitted studies were not evaluated by the Agency, with no explanation. This is contrary to EPA's own guidance and the recommendations made by the National Academy of Sciences.
- Effects determinations were made assuming that product may be applied anywhere in the United States, without consideration of distinctions between use patterns, timing of applications, locations of use, and presence of listed species and critical habitats.
- Compounding of conservatism in the assessment of exposure, resulting in unrealistically high and sometimes physically impossible estimates.
- Failure to consider appropriate lines of evidence, as recommended by the National Academy of Sciences, to determine the likelihood of an effect occurring.

EPA's submission of the BEs in their current form is improper in light of both these facts and the many other critical comments EPA has received from the

OP Registrants, farmers, agriculture organizations, public health officials, professional pest control applicators, and others.

Furthermore, in failing to "explain or support several assumptions critical to its conclusions," EPA violated the Fourth Circuit Court of Appeals' direction that an agency acting to implement the ESA must explain its analysis "with sufficient clarity" to allow stakeholders to determine whether the analysis is "the product of reasoned decisionmaking." *Dow AgroSciences LLC v. Nat'l Marine Fisheries Serv.*, 707 F.3d 462, 464, 475 (4th Cir. 2013). For example, EPA relied on several data sets that it does not dispute are incomplete and/or inaccessible. But it never "cogently explain[ed] why." *Id.* at 473.

EPA sought to excuse its failure to properly revise the drafts or otherwise respond to comments by asserting that the revisions were precluded by a legal obligation to complete biological opinions based upon the BEs by December 31, 2017.[2] That position is incorrect. EPA is not bound by any such obligation.

EPA presumably based its assertion on stipulations entered in court cases by NMFS and FWS. The one of those stipulations to which NMFS was a party did commit NMFS to complete a nationwide OP biological opinion by December 31, 2017. Stipulation and Order to Amend the Stipulated Settlement Agreement Affirmed by this Court on August 1, 2008, *NW Coalition for Alternatives to Pesticides, et al. v. National Marine Fisheries Service*, No. 07-cv-01791 (W.D. Wash., May 21, 2014) ("*NCAP v. NMFS*"), Dkt. No. 50, at 6. But a party to a settlement agreement may request, by motion, that the court modify the settlement agreement for any "reason that justifies relief." Fed. R. Civ. P. 60. Thus, rather than issue flawed BEs, EPA could have asked NMFS to file a motion to modify the *NCAP v. NMFS* settlement agreement deadline so EPA could adequately fulfill its own statutory obligations.[3] Our clients believe there is significant documentation to support a deadline change.

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[2] Office of Chemical Safety and Pollution Prevention's Response to Comments on the Draft Biological Evaluations for Chlorpyrifos, Diazinon, and Malathion, at 2 (Jan. 17, 2017), *available at* https://www3.epa.gov/pesticides/nas/final/response-to-comments.pdf.

[3] FWS entered into an analogous stipulation in *Center for Biological Diversity v. U.S. Fish and Wildlife Service et al.* *See* Stipulation Amending Original Stipulated Settlement and Order, No. 11-cv-5108 (N.D. Cal., July 28, 2014), Dkt. No. 87 ("Amended Stipulated Settlement"). But that stipulation expressly states that FWS "is not obligated to" complete OP consultations by December

Finally, EPA compounded its error by taking the position that it would not revisit these BEs even while acknowledging their shortcomings. EPA cannot dodge its ESA statutory obligation to rely on the "best scientific and commercial data available."[4] At this point, EPA should withdraw the BEs from the Services and leave it to NMFS to address the existing settlement agreement deadline.

We recently have written to Secretaries Ross and Zinke asking that they similarly direct NMFS and FWS, respectively, to return the BEs to EPA and halt any work on preparation of biological opinions based on them, but urge that you not await their actions before withdrawing the BEs.

Thank you for your prompt attention to this request.

Sincerely,

David B. Weinberg

Counsel to Dow AgroSciences, LLC; Makhteshim Agan of North America, Inc., d/b/a "ADAMA"; and FMC Corporation

Enclosures

31, 2017, and it provides that if there were to be a delay the parties would meet and confer to discuss appropriate actions and, if necessary, petition the Court to resolve any dispute. Amended Stipulated Settlement at 4-5.

[4] ESA Section 7(a)(2), 16 U.S.C. § 1536(a)(2).

cc (without attachments except as indicated):

The Honorable Ryan Zinke, Secretary of the United States Department of the Interior
The Honorable Wilbur Ross, Secretary of the United States Department of Commerce
The Honorable Michael Young, Acting Deputy Secretary of the United States Department of Agriculture
The Honorable Jim Kurth, Acting Director of the Fish and Wildlife Service (with attachments)
The Honorable Samuel D. Rauch, III, Acting Assistant Administrator for the National Marine Fisheries Service
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The Honorable Pat Roberts, Chairman, Senate Committee on Agriculture, Nutrition and Forestry
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The Honorable Michael Conaway, Chairman, House Committee on Agriculture
The Honorable Collin Peterson, Ranking Member, House Committee on Agriculture
Dr. Sheryl H. Kunickis, Director, Office of Pest Management Policy, United States Department of Agriculture
Mr. Ray Starling, Special Assistant to the President for Agriculture, Trade and Food Assistance (with attachments)
Mr. Richard Keigwin, EPA OPP (with attachments)
Mr. George Oliver, DAS
Ms. Laura Phelps, ADAMA
Mr. Paul Whatling, FMC

Message

From: Cathy Tortorici - NOAA Federal [cathy.tortorici@noaa.gov]
Sent: 7/13/2018 8:33:03 PM
To: Guilaran, Yu-Ting [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a698774e93e34a2b9181d4b3032b8a32-ytguilar]; Echeverria, Marietta [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=36c56b7169144626bd6aadea25992d4e-Marietta Echeverria]
CC: Tony Hawkes [tony.hawkes@noaa.gov]; Thomas Hooper - NOAA Federal [thomas.hooper@noaa.gov]; David Baldwin - NOAA Federal [david.baldwin@noaa.gov]; Cathy Laetz - NOAA Federal [cathy.laetz@noaa.gov]; Julann Spromberg - NOAA Affiliate [julann.spromberg@noaa.gov]; Daniel Pollak - NOAA Federal [daniel.pollak@noaa.gov]; Shultz, Gina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userd6a2f351]; Craig_Aubrey@fws.gov; Patrice Ashfield [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user1f5a6e17]; pat.shaw-allen@noaa.gov [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user80b35655]; Ryan DeWitt [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=usere2424ebd]
Subject: NMFS RPA/RPM presentation for our July 17, 2018 meeting at 1 pm
Attachments: NMFS BiOp RPA_RPM (7-17-18).pdf; Chapter_26_RPA_&_RPM.pdf; MAgPIE Document.pdf

Dear all -

Here is the PPT in PDF form we will be working off of for our Tuesday meeting.

The EPA concerns mentioned in the presentation come from EPA's February 21, 2018 reinitiation letter.

Ryan will set up a go to meeting for everyone along with a conference line.

We will need the names of all the managers and staff attending the meeting to make sure we include all the right people.

Please respond to this e-mail with that information.

Thanks -

Cathy T.

--
Cathy Tortorici
Chief, ESA Interagency Cooperation Division
Office of Protected Resources
NOAA's National Marine Fisheries Service
1315 East-West Highway
Silver Spring, MD 20910
(w) 301.427.8495
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Mitigating the Risks of Plant Protection Products in the Environment

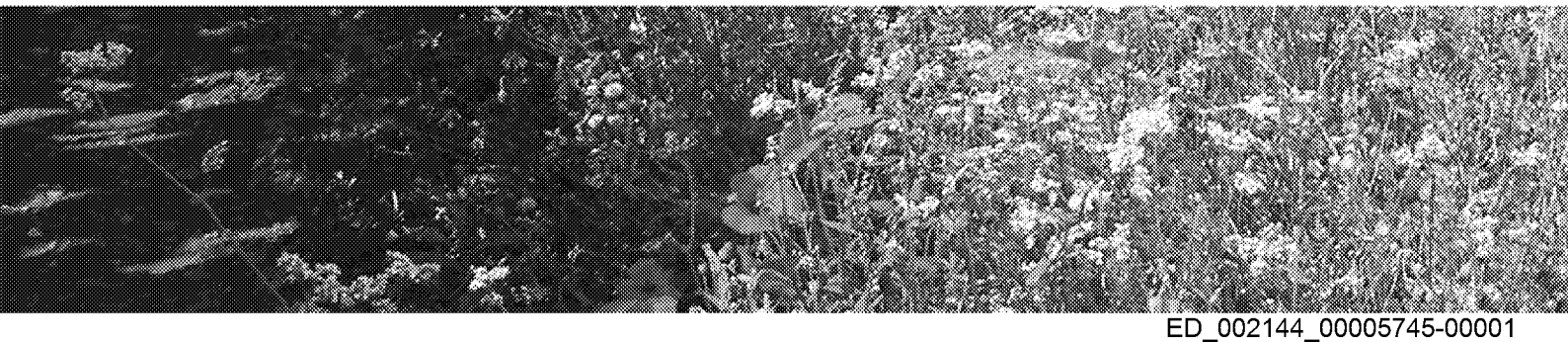
MAgPIE

Editors:
Anne Alix, Colin Brown, Ettore Capri, Gerhard Goerlitz, Burkhard Golla, Katja Knauer, Volker Laabs, Neil Mackay, Alexandru Marchis, Véronique Poulsen, Elena Alonso Prados, Wolfgang Reinert, Martin Streloke

MAgPIE

Mitigating the risks of Plant Protection Products in the Environment

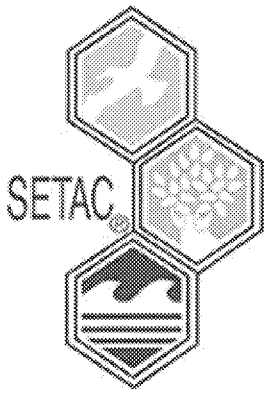
SETAC



MAgPIE

MITIGATING THE RISKS OF PLANT PROTECTION PRODUCTS IN THE ENVIRONMENT

Proceedings of the MAgPIE workshop



Other Titles from the Society of Environmental Toxicology and Chemistry (SETAC)

Pesticide Risk Assessment for Pollinators
Fischer, Moriarty
2014

ESCORT3: Linking Non-Target Arthropod Testing and Risk Assessment with Protection Goals
Alix, Bakker, Barrett, Brühl, Coulson, Hoy, Jansen, Jepsen, Lewis, Neumann, Süßenbach, van Vliet
2012

Ecotoxicology of Amphibians and Reptiles, 2nd ed.
Sparling, Linder, Bishop, Krest
2010

Ecological Assessment of Selenium in the Aquatic Environment
Chapman, Adams, Brooks, Delos, Luoma, Maher, Ohlendorf, Presser, Shaw
2010

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Merrington, Schoeters
2010

Semi-Field Methods for the Environmental Risk Assessment of Pesticides in Soil
Schäffer, van den Brink, Heimbach, Hoy, de Jong, Römbke, Roß-Nickoll, Sousa
2010

Mixture Toxicity: Linking Approaches from Ecological and Human Toxicology
van Gestel, Jonker, Jammenga, Laskowski, Svendsen
2010

Application of Uncertainty Analysis to Ecological Risks of Pesticides
Warren-Hicks, Hart
2010

Risk Assessment Tools: Software and User's Guide
Mayer, Ellersieck, Asfaw
2009

Derivation and Use of Environmental Quality and Human Health Standards for Chemical Substances in Water and Soil
Crane, Matthiessen, Maycock, Merrington, Whitehouse
2009

Linking Aquatic Exposure and Effects: Risk Assessment of Pesticides
Brock, Alix, Brown, Capri, Gottesbüren, Heimbach, Lythgo, Schulz, Streloke
2009

Aquatic Macrophyte Risk Assessment for Pesticides
Maltby, Arnold, Arts, Davies, Heimbach, Pickl, Poulsen
2009

Ecological Models for Regulatory Risk Assessments of Pesticides: Developing a Strategy for the Future
Thorbek, Forbes, Heibach, Hommen, Thulke, van den Brink, Wogram, Grimm
2009

MAgPIE

Mitigating the Risks of Plant Protection Products in the Environment

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Editors:
Anne Alix, Colin Brown, Ettore Capri, Gerhard Goerlitz, Burkhard Golla, Katja Knauer, Volker Laabs, Neil Mackay, Alexandru Marchis, Elena Alonso Prados, Wolfgang Reinert, Martin Streloke, Véronique Poulsen

---

From the two-part SETAC Workshop Mitigating the Risk of Plant Production Products in the Environment

22–24 April 2013
Rome, Italy

13–15 November 2013
Madrid, Spain

Coordinating Editors for SETAC Books

Sabine Apitz
SEA Environmental Decisions, Ltd.
United Kingdom

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C.H. Ward, Rice University
Houston, Texas, USA

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drift, Field Margins (FM) and Compensation Area (CA) aimed at providing food sources and habitat to off-crop flora and fauna, Spray Drift Reduction Technologies (SDRT), which involve any technology associated to sprayers, nozzles, or spraying techniques that will reduce the drift, Dust Reduction Technologies (DRT), which involve any technology associated with seed coating, granule manufacture, or drillers to reduce the abrasion of seeds or granules at drilling or to reduce the spread of dust out of the cropped area, Good Agricultural Practices (GAP), which relate to product application (dose and application regime), Crop Management (CM), which relates to agricultural practice in the crop or the field margins aimed at reducing a source of exposure or transfer route, and Bee Management (BM), which relates specifically to measures applied to managed bees to keep them from exposure. The corresponding Risk Mitigation Measure Technical Sheets (RMMTS) are listed in the last column together with their location in the proceedings

Table 6.3 Evaluation and ranking of multiple benefits of different field margin types (NR = natural regeneration, GR = grass sown, WF = wildflower sown, P&N = pollen and nectar mix, WBS = wild bird seed mix, AC = annual Cultivation, CH = conservation headland)

Table 6.4 Outcome of 80 studies on the effects of flowering strips on wildlife and biodiversity, adapted from Dicks et al. (2013). Sixty-four studies showed some benefits to one or more wildlife groups. Note that numbers do not sum up as effects could be positive, negative, or neutral on different species or groups in the same study

Table 7.1 Overview of the risk mitigation measures (RMM) suitable to reduce environmental risks in farmland. RMM are allocated into the following categories: Good Agricultural Practices (GAP), which relate to product application (dose and application regime), Crop Management (CM), which relates to agricultural practice in the crop or the field

margins aimed at reducing a source of exposure or transfer route, and Bee Management (BM), which relates specifically to measures applied to managed bees to keep them from exposure, Buffer Zones (BZ) aimed at reducing exposure of off-field area via spray drift, Field Margins (FM), and Compensation Area (CA), aimed at providing food sources and habitat to off-field flora and fauna, Seed Treatments and Granules (STG), which involve any technology associated to seed and granule applications. The corresponding Risk Mitigation Measure Technical Sheets (RMMTS) are listed in the last column together with their location in the proceedings

Table 7.2 Overview on possible compensatory measures for mitigating the risk to farmland birds caused by PPP-related alteration of the food web

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Table 10.1 Examples of existing stewardship initiatives and activities in Europe. The focus area describes the purpose or protection objective of the activity, within one of the following category: general farming practices, protection of biodiversity, protection of pollinators, and protection of water quality. Initiative or activities may provide various services organized here as advice, education, training, information, mapping tools, or funding. The main audience is often farmers however, the information is public and accessible to all

Preface

Anne Alix, Wolfgang Reinert, and Martin Streloke

"To protect aquatic organisms, respect an unsprayed buffer zone of 3 meters to surface water bodies"

This simple phrase usually appears on the labeling of a pesticide container, which provides a farmer with directions for use, explicitly how to spray his field with this specific product. Although the phrase uses simple wording and provides rather precise instructions, one would be surprised by the number of questions, and requests for clarification that such a phrase triggers in farmers for their agriculture advisers, in agriculture advisers for their regulatory authorities, and between regulatory authorities in different European countries. It sounds simple, yet what is a buffer zone? Is it inside or aside the limits of a field? Does it start with the last spraying nozzle, or at the edge of the spraying cone? Does it take into account the water body bank? Does the phrase also apply if I use spray drift reducing nozzles? Hence, the safety precaution phrases of the European Regulation 547/2011 from which the above phrase is extracted have been implemented in European countries alongside a number of adaptations for them to match with the farming practices, national legal frameworks and in some cases, the definition of what describes a water body on national maps! In the meantime and over the years, European countries have also worked at increasing the level of environmental safety of the pesticides used in agriculture, and developed new tools or risk mitigation measures to complement the set of measures listed in the European regulation. Yet the step towards the implementation of these new measures, by farmers and through pesticide labeling, faced three main hurdles:

- *Is the new measure supported by science?*
- *Is the measure practical enough to be easily implemented by farmers?*

- *Is the measure suitable for neighboring countries and therefore supports mutual recognition of authorizations?*

This book gathers the essence of the extensive discussions that took place over two workshops and 3 years of intensive work and data analysis by 95 experts and regulators from 24 European countries. The richness of the exchanges is reproduced in the main volume and in its equally long appendix that attempts to provide the reader with a comprehensive view on the state of risk reduction and risk mitigation in cultivated landscapes. Gathering 24 countries to reach a consensus on a genuinely diverse, often considered "case-specific," scientific topic that is influenced by local conditions, although challenging, proved to be an unbelievably enlightening journey across European landscapes. We recorded farming practices and their evolution and met the diversity of scientists, technicians, and regulators, all passionate about a common objective: translating science into applicable solutions to farmers for a safer use of pesticides for the environment.

With the publication of this book the first step towards an efficient harmonization of risk mitigation measures is done. The legal implementation of common risk mitigation measures in Europe needs some further efforts of the Member States to create a harmonized risk management system in Europe.

Acknowledgements

This publication was generously sponsored by the following organizations:

ECPA – The European Crop Protection Association
BASF
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Dow AgroSciences
Dr Knoell
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National Institute on Agronomy (INIA)
Makhteshim Chemical Works Ltd
Monsanto
The Office for Agriculture Switzerland
RifCon
Syngenta

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The European Commission
National Institute on Agronomy (INIA), Spain
OPERA Research
The University of Milan

About the Editors

Anne Alix

Anne Alix is a senior scientist in the area of environmental risk assessment and risk management. She earned a Ph.D. in Biology and Integrated Pest Management in vegetable crops in 2000 at the University of Rennes in France. She joined the French National Institute on Research in Agronomy (INRA) as an ecotoxicologist in 2001, and served as the head of the Environment and Ecotoxicology unit at the French Agency on the Safety of Food (AFSSA, now ANSES). At the French Ministry of Agriculture, Anne linked risk assessment to risk management as the deputy head of the Section for Regulation and Placing Plant Protection Products on the Market, where she lead the implementation of risk mitigation measures for pesticides and post registration monitoring. Anne joined Dow AgroSciences in 2011, as their European Regulatory Risk Management Leader. She has worked with a number of expert groups to develop risk assessment methodologies in diverse environments, some through workshops such as such as ELink, Focus Landscape and Mitigation, and ESCORT 3, and through SETAC groups, such as the MODELINK workshop and the Environmental Monitoring Interest Group on Pesticides.

Colin Brown

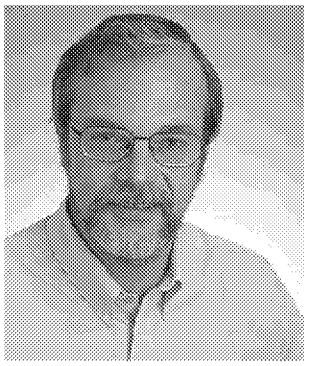
Colin Brown is Professor of Environmental Science within the Environment Department at the University of York. He has more than 25 years' experience of research into the fate and effects of pesticides in the environment. Colin has advised the UK government on the environmental fate and behavior of pesticides through membership of the Advisory Committee on Pesticides and chairing its Environmental Panel. He has chaired the DG-Sanco FOCUS working group on Landscape and Mitigation Factors in Ecological Risk Assessment for Pesticides and Chairs

the conference on Pesticide Behavior in Soils, Water, and Air held every four years in York.

Ettore Capri

Ettore Capri earned his Ph.D. in Chemistry, Biochemistry and Ecology of Pesticides at Milan University in 1992. That same year he became a scientist in Environmental and Agricultural Chemistry at the Catholic University, and full Professor in Agricultural Chemistry in 2002. His research concerns the ecotoxicology, environmental chemistry, and consumer risk from pesticides, nutrients, heavy metals and trace elements. Ettore's current research is focused on how to integrate the chemical risk from the environment to the human and how to bridge the science to policy. In 2012, the Italian Ministry of the Environment assigned Ettore the responsibility of developing a program for the sustainable development of the wine production sector that included environmental labeling. Since 2009 he has been a member of the Ministry of Agriculture and Forestry on Integrated Food Production. He has also served as a member of the MIUR Commission on Food Education for Expo2015. Other prominent positions include member of the Global Food Ethic Project of The Johns Hopkins Berman Institute of Bioethics (since 2014), member of the Advisory Committee of the University of California Davis Institute for food and Agricultural Literacy (since 2014), formal member of the Panel on Pesticide Risk Assessment of the European Food Safety Authority (2005 – 2015). Ettore has served as Director of the Research Center on Sustainable Development OPERA since 2009, contributes to think tanks in Brussels, and while in Piacenza ideates research projects on education, training, dissemination, and communication. He has published about 230 scientific papers & communications and edited several books. He is an Associate Editor on the scientific journal Science of Total Environment published by Elsevier.

Gerhard Goerlitz



Gerhard Goerlitz studied Chemistry at the University Saarbrücken and went on to earn a Ph.D. at the Institute of Applied Physical Chemistry. Gerhard has worked from 1982 at Hoechst AG and its successor companies Agrevo and Aventis CropScience as an Analytical Chemist, Head of the Product Analysis Group, and Head of Analytics and Quality Management. In 2002 he became Head of Environmental Modeling at Bayer AG - Crop Science Division, located in Monheim, Germany. He started environmental modeling of plant protection products in the late 1980s and has since actively worked in this field. He has participated in several international projects including, COST66, EUFRAM, and ELINK. Since its foundation in 1994, he has been a member of the FOCUS Steering Committee. Presently, he chairs the ECPA Environmental Exposure Assessment Team (EEAT). He was involved in the EFSA project on emissions from protected crops as a Hearing Expert and participated in several stakeholder workshops on the topic.

Burkhard Golla

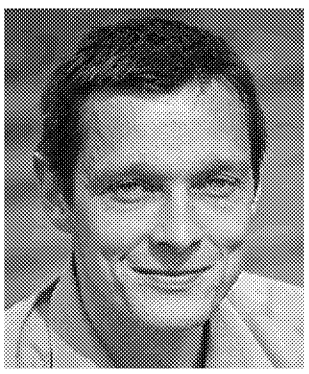
Burkhard Golla is a senior research scientist at Julius Kühn-Institute (JKI), Federal Research Centre for Cultivated Plants, Germany. His research focuses on GIS-aided methods to evaluate the risks and benefits of pest and crop management strategies. He is particularly interested in spatially explicit exposure assessment of pesticides at landscape level.

Katja Knauer

Katja Knauer works for the Federal Office for Agriculture in Switzerland and is in charge of the scientific evaluation of dossiers for the authorization of plant protection products and environmental risk management. She is further responsible for the Swiss action plan for bee health and involved in the development of the Swiss action plan on the suitable use of plant protection products. Katja has participated in various SETAC workshops addressing topics such as quality standards for water and soil, ELINK- linking

exposure to effects, and AMRAP- aquatic plants in the aquatic risk assessment. She has served as a member of the SETAC Europe Council and is still actively involved in the science committee. Katja received her Ph.D. in Environmental Sciences at ETH Zürich, Switzerland, and conducted a postdoc at the Massachusetts Institute of Technology in Boston and at the University of Geneva. She worked as an environmental risk assessor at Syngenta on the ecotoxicological effects of plant protection products in support of applications for Registration.

Volker Laabs



Volker Laabs currently works for the Crop Protection Division of BASF SE based in Limburgerhof, Germany. He is responsible for the Global Product Stewardship Team and serves his company as water expert. He is a member of the Water Expert Group at the European Crop Protection Association and chairman of the TOPPS Water Protection multi-stakeholder project. Volker received his degree in Geoecology and his Natural Science doctorate from Bayreuth University, Germany. His research interests concern the fate of crop protection products and pharmaceuticals in the environment, and the function of biochar in soil and its influence on soil fertility.

Neil Mackay

Neil Mackay is a senior research scientist in the environmental safety assessment group of DuPont Crop Protection. Neil is active in strategic product development and regulatory exposure and risk assessment activities. His specific interests include aquatic risk assessment and the use and promotion of practical and effective drift mitigation strategies.

Alexandru Marchis

Alexandru Marchis holds a Ph.D. in Agricultural Policies and has an academic background in agricultural economics with two post university degrees in Agribusiness and in Diplomatic International Relations. He has collaborated with Universita Cattolica del Sacro Cuore in Milan since 2010 and is in charge of the research outreach on agriculture and food issues. He has also been the Policy Team Coordinator of the OPERA Research Center agricultural think-tank and is a successful consultant for private entities in the area of food and agriculture policies. Since November 2014, Alexandru has been the coordinator of the UNCCD Soil Leadership Academy project. He previously held the position of Counselor for European Affairs in the Ministry of Agriculture in Romania. In 2005, he was appointed Agricultural Attaché and the Permanent Representation of Romania to the EU.

Elena Alonso Prados

Elena Alonso Prados works in the Plant Protection Unit of The National Institute for Agricultural and Food Research and Technology in Spain. (INIA). Between 2002 and 2010 she worked on the environmental fate and behavior assessments of active substances of plant protection products, participating as an expert in the European peer review process. Nowadays she is team leader responsible for the evaluation of the environmental fate and behavior and ecotoxicology sections of EU and zonal dossiers under regulation 1107/2009.

Véronique Poulsen

Véronique Poulsen has 20 years experience as an ecotoxicologist. She heads the Ecotoxicology and Environmental Fate Unit in the Regulated Products Assessment Department at ANSES (French Agency for Food, Environmental and Occupational Health Safety). She obtained her Ph.D. in conducted research on aquatic microcosms at INERIS (National Institute of Industrial Environment and Risks), France. Her team of 30 ecotoxicologists and environmental risk assessors is in charge of the

risk assessment of pesticides prior to their authorization. She has helped organize many EU and international workshops related to pesticide risk assessment methodology, topics that include aquatic macrophytes, bees, endocrine disruptors, non-target terrestrial plants, and ecosystem services and their regulation.

Wolfgang Reinert

Wolfgang Reinert is a Biologist and was trained in Soil Biology. He worked in research and advisory service for plant pathology and plant breeding. In 2002, he joined the unit in charge of approving active substances and placing plant protection products on the market at the European Commission. Wolfgang has led the sector for pesticide market placing since 2014.

Martin Streloke

Martin Streloke is the head of the Department of Plant Protection Products at the Federal Office of Consumer Protection and Food Safety (BVL) in Germany. He completed his Ph.D. in zoology and entomology at Hanover University. Martin has 25 years of professional experience in the field of risk assessment and risk management in the context of authorization procedures for plant protection products in Germany. He participated in the preparation of EU-guidance documents and he chaired expert meetings for the approval of active substances in the EU-regulatory system. He was also taking part in different OECD Working Groups and was a member of the SETAC Europe Council.

Workshop Participants

Participants were assigned to one of the four working groups listed below based on their area of expertise in the different categories of identified risk mitigation. The working group discussion objectives are presented in the introduction of these proceedings, and the outcomes are summarized in the following chapters. The proceedings reflect the input shared by

each participant during the workshops, however it does not imply that each participant endorses each and every risk mitigation tool listed, as reflected by the diversity of approaches used in Member States. The workshop participants propose developing state-of-the-art risk mitigation tools to be developed in Member States, and recommend further harmonization and implementation within EU countries.

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List of Abbreviations

AES	Agri-Environmental Scheme (of the CAP)
ALMASS	Animal, Landscape and Man Simulation System
BASIS	Independent standards setting and auditing ertilizern for the pesticide, ertilizer and allied industries
BM	Bee Management
BVL	Biologische Bundesanstalt fur Land- und Forstwirtschaft,ssortenamt unde Chemische Industrie
BZ	Buffer Zone
CA	Conservation Area
CAP	Common Agricultural Policy
CFE	Campaign for the Farmed Environment
CRD	Chemicals Reglation Directorate (Directorate of the Helath and Safety Executive responsible for ensuring the safe use of biocides, industrial chemicals, pesticides and detergents in the UK)
DAFM	Department of Agriculture, Food and Marine
DAR	Draft Assessment Report
DEFRA	Department for Environment, Food and Rural Affairs
DRR	Draft Registration Report
DRN	Drift Reducing Nozzles
DRT	Dust Reduction Technology
EC	European Commission or European Council

ECAF	European Conservation Agriculture Federation in Ireland
ECPA	European Crop protection Association
EFSA	European Food Safety Authority
EU	European Union
GAP	Good Agricultural Practices
GIS	Geographic Information System
IAD	Institut de l'Agriculture Durable
IBM	Individual Based Model
ICM	Integrated Crop Management
INSPIA	European Index for Sustainable Productive Agriculture
IPM	Integrated Pest Management
IVA	Industrieverband Agrar (German Agricultural Industry Association)
JKI	Julius Kuhn Institute
LEAF	Linking Environment and Farming
LERAP	Local Environment Risk Assessment for Pesticides (in the UK)
MASTEP	Metapopulation model for Assessing Spatial and Temporal Effects of Pesticides
MODELINK	Workshop on How to Use Ecological Effect Models to Link Ecotoxicological Tests to Protection Goals
MS	Member State
MSG	Metaldehyde Stewardship Group
NAP	National Action Plan
NFU	National Farmers Union in the UK

NGO	Non-Governmental Organisation
OECD	Organisation for Economic Cooperation and Development
OP	Organo phosphate
PEC	Predicted Environmental Concentration
PPP	Plant Protection Product
RMM	Risk Mitigation Measure
RMS	Rapporteur Member State
RR	Registration Report
RRMTS	Risk Mitigation Measure Technical Sheet
RSPB	Royal Society for the protection of Birds
SANCO	Health And Consummer Protection Directorate-General, European Commission
SDRN	Spray Drift Reducing Nozzles
SDRT	Spray Drift Reduction Technology
SETAC	Society of Environmental Toxicology and Chemistry
SP-Phrases	Safety Precaution Phrases (of Regulation (EU) 547/2011)
SSSI	Site of Special Scientific Interest
SUD	Sustainable Use Directive (Directive (EC) 2009/128)
TOXSWA	TOXic substances in Surface WAters
VFSMOD	Vegetative Filter Strip Modeling System
WFD	Water Framework Directive (Directive (EC) 2000/60)

1 Executive summary

Environmental risk mitigation measures are a key component in defining the conditions of use of pesticides in crop protection in Europe (EC 2009a, 2011). These risk mitigation measures are derived directly from the evaluation of pesticide products and the risk assessment conducted for each use, and are specific of the type of risk they intend to mitigate. They therefore range from the adjustment of the conditions of use to minimizing transfers to groundwater to the setting of buffer zones at the edge of the crop. Once defined, these measures are reported on the labeling in the form of Safety Precaution Phrases (SP-phrase), according to Regulation (EU) No. 547/2011 (EC 2011) for implementation in European Member States (EC 2015).

In Europe, Member States have developed their own risk mitigation measures, which respond to the agricultural practices in the country, but are also incorporated into legal framework at the national level. Although locally effective, the genesis of a wide variety of approaches proved to raise issues regarding divergence of interpretation and, when access to risk mitigation tools differ between neighboring countries, a potential for concurrence distortion issues.

In this context, a two-part workshop was organized in April and November 2013, under the auspices of the Society of Environmental Toxicology and Chemistry (SETAC) and the European Commission. The goal of the workshop was to develop a toolbox of risk mitigation measures designed for the use on pesticides for agricultural purposes, and thus contribute to better harmonization of their development and use within Europe. Participants included risk assessors and risk managers from 24 European countries, plus experts from Norway and Switzerland, and representing participants from the business sector, academia, and agronomical advisors and extension services.

Workshop discussions started with an inventory of the environmental risk mitigation measures in use in European countries, compiled from a questionnaire survey circulated prior to the meetings. Risk mitigation

tools in use for groundwater, surface water (including the protection of aquatic organisms), off-crop areas and in-crop areas were collected and each tool was described with regards to its level of implementation, technical description, regulatory status, inclusion in the good farming practices, economical considerations, options to measure its effectiveness, and finally, options to be taken into account into the regulatory risk assessment. This inventory is summarized in Table 1.1.

Table 1.1: Risk mitigation tools inventoried in European countries, Norway, and Switzerland as a result of the MAgPIE workshop, together with their benefits and related regulatory framework

Type of Mitigation Measure	**Risk Mitigation Measure**	**Benefits**	**Regulatory Framework**
Restrictions or modifications of products' conditions of application	Application rate, application frequency, application timing, and interval between applications	Lower transfers to groundwater and surface water Reduces exposure of organisms in-crop and off-crop	Regulation (EC) No. 1107/2009 and Regulation (EU) No. 547/2011
Application equipment with Spray Drift Reduction Technology (SDRT)	Spray drift reduction nozzles (SDRN), shields, precision treatment, etc.	Reduces exposure of organisms in-crop (precision treatment) and off-crop	Regulation (EC) No. 1107/2009, Directives 2009/1285 and 2009/1276
Buffer zones	Non-sprayed zone at the edge of a crop	Reduces exposure of organisms in-crop and off-crop	Regulation (EC) No. 1107/2009 and Regulation (EU) No. 547/2011, Directive 2000/607, Directive 92/438
	Vegetated	Reduces exposure of	Regulation (EC) No.

Field margins	buffer strip	organisms in-crop and off-crop, and provides habitat and food resource	1107/2009 and Regulation (EU) No. 547/2011, Directive 2000/607, Directive 92/438
	Multifunctional field margin	Reduces exposure of organisms in-crop and off-crop, provides habitat and food resource, and mitigates effects on biodiversity	Regulation (EC) No. 1107/2009 and Regulation (EU) No. 547/2011, Directive 2000/607, Directive 92/438
Compensation areas	Recovery areas (ecological focus areas)	Provides habitat and food resource, reduces exposure of organisms in-crop, and pending on location in the farmland, may reduce exposure of organisms off-crop	Regulation (EC) No. 1107/2009 and Regulation (EU) No. 547/2011, Directive 2000/607, Directive 92/438, CAP
Dust drift reduction technologies	High quality coating, low dust drillers	Reduces exposure of organisms in-crop and off-crop	Regulation (EC) No. 1107/2009 and Regulation (EU) No. 547/2011
Bee management	Bee hive removal or protection, application periods, information to beekeepers	Managed bees	Regulation (EC) No. 1107/2009 and Regulation (EU) No. 547/2011

This inventory confirmed the diversity of the tools developed and implemented throughout European countries, as well as the number of regulatory frameworks to which they relate or with which they may overlap.

On the basis of this analysis, each tool was then allocated into one of the following categories:

1. Not to be promoted
2. Under development
3. Needs consolidation and research
4. Promising tool implemented in some Member States
5. Well established tool implemented in most Member States

The toolbox was then built to gather the risk mitigation options belonging primarily to the fourth and fifth categories, and the detailed technical data supporting each tool were gathered and discussed in order to provide the users of the toolbox with technical recommendations in view of future implementation. These data are contained in the Risk Mitigation Measure Technical Sheets (RMMTS) for the risk mitigation tools that are already implemented in most Member States, and in Technical Advice Sheets for the most promising tools for which an implementation could be initiated at a broader scale.

In each working group a thorough investigation of Safety Precaution Phrases relevant for protecting the environment of Regulation (EU) No. 547/2011 has shown that some of these phrases might be adjusted to help Member States in setting appropriate risk mitigation measures. Furthermore, it should be considered whether a European guidance document on setting risk mitigation measures should be prepared in order to describe a clear framework for Member States facilitating the use of European-wide, harmonized label phrases. Workshop participants proposed that the core assessment of a product's evaluation, the need for risk mitigation, and the level of risk mitigation need to be reported. Following group discussions, participants felt that in general, the exact level of risk reduction needed was not required, but rather a grouping of risk in classes would facilitate the regulatory work and communication with farmers. Classes of 50, 75, 90 and 95% risk reduction are well established, and in some cases 99% was considered possible if scientifically based. Then these risk classes may call for a single risk mitigation measure or a combination of different risk mitigation measures as illustrated for runoff or spray drift in the proceedings. The existing

Safety Precaution Phrases were reviewed in this context, in order to account for the proposed risk mitigation tools. New and revised SPe (SP-phrase specific to the environment) or SPr (SP-phrase specific to mode of action) phrases were drafted to better reflect the diversity of the options offered to users to mitigate risks and improve the clarity of the directions provided.

The workshop also discussed options to optimize the implementation of risk mitigation measures, in particular with regards to possible overlaps among different regulatory texts (e.g., regulatory frameworks relative to plant protection products and the Water Framework Directive), and with regards to the options to further develop the multifunctional aspects of risk mitigation measures, as for field margins. Finally, transversal aspects relative to the protection of biodiversity were discussed.

It is important to note that all data and information made available up to March 2015 were included after it was decided with proceed to the preparation of these proceedings.

1.1 Risk mitigation measures to protect surface water

1.1.1 Runoff mitigation

Abundant scientific evidence has been published regarding the effectiveness of various runoff risk mitigation measures. Consequently, vegetated buffer strips that have been in use for aquatic regulatory risk assessments in several Member States for years and various other runoff risk mitigation measures are now available to be included in a European toolbox. On the basis of our analysis of available data the following basic runoff risk mitigation toolbox is identified, for which general effectiveness values are available:

Table 1.2: Basic toolbox list of runoff risk mitigation measures

Type of Mitigation Measure	**Risk Mitigation Measure**
In-field	Vegetated filter strip, across slope (5 m width)

	Inter-row vegetated filter strips in permanent crops
	In-field bunds for row crops (e.g., potatoes)
	No-till or reduced tillage
Edge-of-field and off-field	Vegetated filter strip (5 m, 10 m, and 20 m width)
	Artificial wetland or retention pond
	Vegetated ditches
	Edge-of-field bunds

For each of these tools, advice for alternative integration into product-specific modeling approaches were developed, and can be adapted to country-specific conditions, as needed. Many factors influence runoff, and the toolbox herein proposed accounts for the fact that the highest mitigation effectiveness and efficiency is achieved when farmers have the option to select the measure(s) most fitting to their field conditions and crop rotations.

A flexible toolbox approach is the most appropriate way to support European Member States' implementation of runoff mitigation tools. This flexible toolbox first considers the level of runoff risk mitigation needed, as calculated for a product and representative use, e.g., at zonal level. Then Member States are offered the option of implementing the risk mitigation measures of the toolbox at the management level, or after their inclusion into a risk assessment:

- At the risk management level: Based on the runoff mitigation need stated on the label (in %, or transposed into runoff mitigation points), farmers choose a single or multiple measures with defined average effectiveness from an official list to achieve the required effectiveness
- After inclusion into the risk assessment process: Based on the runoff mitigation need, modeling evaluates different measures and combinations thereof to achieve the required overall effectiveness

(%). All eligible measures and combinations are then listed for this product on the label

Whatever the preferred approach is to a Member State, there remains a need to establish a list of accepted runoff mitigation measures at the national level, which also details good practices for establishment and maintenance for each measure in order to enable auditing in the field.

1.1.2 Spray drift mitigation

A number of options for spray drift mitigation exist, which include:

- Buffer zones at the edge of fields
- Vegetated buffer zones or strips
- Spray Drift Reducing Technologies (SDRT) including, Drift Reducing Nozzles (DRN), and other machinery equipment such as shield sprayers, tunnel sprayers, band sprayers, and precision sprayers

However, our inventory revealed an uneven implementation of these measures, due to differences in national policies, as well as in the the acceptance of techniques and measurement standards. Overall, this currently limits the opportunities to exploit the efficiency of a harmonized framework of risk mitigations.

These limitations however, may be overcome through a combination of flexible risk assessment options and labeling, allowing the implementation of local policies. A similar approach to the one developed for runoff could be considered. As for runoff, the first step would be to agree on the level of risk reduction that is needed for a specific risk. For example, if a specific risk triggers a 75% reduction exposure to be mitigated, the reduction may be provided by implementating a buffer zone, or with drift mitigation techniques adapted to local policies and standards, and providing the equivalent level of drift reduction.

The development of a basic harmonized basis for the acceptance of spray drift reduction technology (SDRT) efficacy thresholds (e.g., 50%, 75%, 90%, and 95% effectiveness) is then recommended. The extension to measures allowing a 99% drift reduction would stimulate and anticipate further technological advances and allow for options of compounded

mitigation.

1.1.3 Drainage risk mitigation

Surface water can be contaminated by pesticides through drainage, which therefore triggers the need for dedicated risk mitigation measures. However, the processes dominating the transport of pesticides into the drainage system are closely related to those determining the leaching into groundwater. Consequently, the participants concluded that almost all the measures discussed for mitigating groundwater risk were also suitable for mitigating exposure via drainage water. These include restrictions on application rate or timing, soil type, band application, restriction of use in vulnerable areas.

As for groundwater, modeling approaches based on approved regulatory models and scenarios can be used to evaluate the effectiveness of a mitigation measure under specific circumstances. If the conditions leading to increased drainage differ from those that increase leaching to groundwater, a separate evaluation may ne needed in order to determine the effectiveness of a mitigation measure under specific circumstances.

Measures such as retention ponds and artificial wetlands were discussed, as well. They may constitute an effective measure at Member State-level where the volume of drainflow is limited, and they often involve large structure. Therefore, the evaluation of their effectiveness was considered premature, as they are not yet sufficiently documented.

1.2 Groundwater protection

The most popular measures in European countries (implemented in more than half of the European Member States) include application restrictions as a function of plant growth stages. Limitations may restrict the maximum number of applications per year or within a two- or three-year period and may be relative to the type of soil or to soil hydrological properties. These risk mitigation measures can be easily taken into account in the risk assessment. Their regulatory, technical, and agronomical feasibility is high and they can be easily enforced. The effectiveness of these measures with regard to groundwater protection can generally be quantified by the use of established regulatory tools,

especially leaching modeling.

Measures such as restricting application to certain periods of the year or to a portion (bands) of the cropped area and restricting use in drinking water exclusion areas are also reported to be implemented in 30% to 50% of the Member States. These measures also present a high feasibility and agronomical practicability and they can easily be taken into account in the risk assessment using approved models and scenarios. Restrictions in drinking water abstraction areas are practiced in more than 30% of the Member States, but most often in the context of other legislation and dependant on the interpretation of the set of legislation at national level.

Exclusion of zones with certain hydrogeological properties, e.g., carstic areas, are in use in some Member States and rely on the definition of the corresponding zones in a country. It was suggested that these zones could also be identified and defined jointly with exclusion zones based on vulnerability maps and catchment management plans.

Finally, the use of cover crops during the winter period or inter-row crops as a risk mitigation option for groundwater raised particippants' interest, as the crops may provide additional benefits for soil conservation and for the reduction of nitrate leaching. However, we agreed that the effectiveness and practicability of these options need more investigation before their inclusion in our toolbox.

1.3 Protection of in-crop areas

We considered the groups of organisms common to agricultural areas, such as birds, mammals, bees, non-target arthropods, soil organisms (i.e., earthworms, soil macro- and micro- organisms), and, put in the context of a cropped area, biodiversity when discussing risk mitigation in-crop.

The most popular risk mitigation measures in Member States are those with quantifiable effectiveness: collectable incorporation rates (for sprayed or seed or soil treatments) and reduction in the application rate or of the number of applications.

With regards to birds and mammals, the measures already in use in Member States include the avoidance of spreads for granules and treated seeds and specific precautions to be taken for products presenting

toxicological patterns of concern such as rodenticides, molluscicides, and baits. In addition, conditions of use relative to the breeding period, or regarding the rate or frequency of applications are also already in use, and covered by specific Safety Precaution Phrases.

With regards to honey bees, the inventory revealed a widespread implementation of the measures recommended in Regulation (EU) 547/2011 (EC 2011) for example, restrictions of use in flowering crops, management of hives, and specific measures relative to coated seeds. Recommendations regarding the removal of flowering weeds in perennial crops was discussed and further documented through a literature review. The review was unable to conclusively show the benefits of removing flowers in cultivated areas. The main concern was the food limitation stress imposed on pollinating species versus the exposure reduction it theoretically provides.

The measures that address non-target arthropods used by Member States include restriction or modifications of application rates or frequency of applications, to allow recovery in the treated area. Applications on a fraction of the crop have also been recommended, as well as the introduction of unsprayed headlands.

With regards to soil organisms (micro- and macro-organisms), the risk mitigation measures in use in Member States are limited to restrictions of the application rates or frequency, to allow the recovery of the affected taxa.

Additional options to reduce risks to in-crop populations are provided in the list proposed for the off-crop area, particularly in the category of field margins, which provide reservoirs and habitat to an ensemble of organisms in the farmland. Although the effectiveness of these measures at reducing risks is not yet characterized on a quantifiable way, it was agreed that the generation of monitoring data through field studies or monitoring programs could demonstrate their effectiveness through records of limited or non-significant effects of the product, even if the risk reduction cannot be strictly quantified. This is also valid for generic mitigation measures, i.e., those not related to a product, but implemented in the context of agri-environmental measures with an aim to maintain or improve the environmental status of an area, as for example in the context of the Commom Agricultural Policy. These

measures include all types of landscape management and as such may provide generic risk mitigation on the area covered. Again, the effectiveness of those measurements can be observed in field studies or field monitoring programs and recommendations were made accordingly.

Finally, special attention was given to compensation measures and their potential to contribute to the reduction of the pressure of in-crop organisms from agricultural practices and pesticides. The survey performed in Member States does not report examples of an implementation of compensation measures in the context of pesticide management, however potential overlap between these farmland management measures and risk mitigation options for pesticides were discussed.

1.4 Protection of off-crop areas

The toolbox for the protection of the off-crop area gathers a diversity of options as summarized in the table below:

Table 1.3: Toolbox for risk mitigation for off-crop organisms

Type of Mitigation Measure	**Risk Mitigation Measure**	**Category of Risks That May Be Reduced**
Buffer Zone	No spray zone, wind-dependant no spray zone, bare soil, landscape-dependant buffer zones, aerial treatments	All organisms from exposure to spray drift
Field margin	Vegetated buffer zone	All organisms from exposure to spray drift or runoff Provides habitat and food resource
	Multifunctional field margin	All organisms from exposure to spray drift or runoff

		Provides habitat and food resource
Compensation areas	Recovery areas (ecological focus areas)	All organisms from exposure to spray drift or runoff (pending on location) Provide habitat and food resource
Spray drift reduction technologies	Nozzles (SDRN), equipped sprayers, directed spray, precision treatments	All organisms from exposure to spray drift
Dust drift reduction technologies	High quality coating, low dust drillers	All organisms from exposure to dust drift
Conditions of application	Application rate and frequency management	All organisms from exposure to drift or runoff
Bee management	Bee hive removal or protection, application periods, information to beekeepers	Bees

The most frequent risk mitigation options used in all Member States are the implementation of buffer zones and non-sprayed zones at the edge of treated crops, besides Spray Drift Reduction Technologies and specific restrictions (or modifications) on the conditions of use of pesticides, already described for groundwater, surface water, or in-crop protection.

Special attention was given to farmland features, such as field margins management, and to their potential as risk mitigation measures as observed in the monitoring studies that investigated their effectiveness in the context of the implementation of agri-environmental schemes. A variety of field margin types have been described, such as natural regeneration areas, grass margins, wildflower margins, pollen and nectar or bird seed mix field margins, annual cultivation areas, and conservation headland. The benefits of these measures are documented in monitoring studies based on abundance and diversity indexes of in-crop and off-crop

populations and communities. From these studies, we explored the relative benefits for diverse aspects relative to the group of "organisms of concern" through an evaluation and ranking exercise. We agreed that this first analysis conducted in the context of the workshop was useful to obtain insight to which benefits each feature provides to specific groups of organisms, but that more research was needed to refine the knowledge and allow their inclusion in the risk assessment. The analysis highlighted the importance of developing the multi-functionality of field margins as a way to optimize their land use by the farmers who implement them as risk mitigation measures. It is critical to promote the implementation of these types of field margins in order for the benefits they provide on the groups of organisms and processes listed above to be seen rapidly. As we observed in the available studies, their benefits are more significant at a larger scale, and landscape approaches may be more effective than field-scale implementation. This is important when deciding upon the most appropriate policy level for implementation in individual countries.

Workshop participants agreed that consensual monitoring of the varied approaches is needed to quantify the effectiveness of the measures once implemented. This monitoring, coupled with GIS-based databases, is needed to appreciate the environmental status of a landscape, which helps refine the recommendations in the RMMTS relative to field margins and farmland landscape features to be implemented.

Finally, a discussion of these risk mitigation measures in the broader context of agri-environmental measures that are already implemented within the Common Agricultural Policy will be critical to avoid duplicated efforts by farmers while ensuring the development of optimized farmland management options.

1.5 Recommendations

The inventory undertaken by the different working groups identified the data sources that support the risk mitigation included in the toolbox. The data are collated in the appendices (Volume 2) of this work and identify the major sources of research and development in the area. Further work is indeed needed to 1) accompany the implementation of the risk mitigation measures in countries, 2) consolidate the data sets supporting

some of the measures and their potential improvement, and 3) support the development of the risk mitigation identified as promising, but considered as not yet ready.

The needs in terms of actions and development are listed below. Participants shared the hopes that the proposed measures, as well as the measures to be further developed, will provide farmers and regulatory authorities with a fair and practical toolbox, which is important to their acceptance in both parties. These recommendations are more completely listed listed in Chapters 4 – 10.

1. Encourage the implementation of the toolbox in order to benefit of the risk mitigation these tools can already provide and collect further quantification of their effectiveness, as well as on the practicality of their implementation

2. Pursue the development of fair and effective environmental risk mitigation measures easy to implement in the decision making process, e.g., via the Safety Precaution Phrases, and by farmers

3. Develop the multi-functionality of field margins and adapt to Member States conditions in order to optimize the associated benefits

4. Develop a dialogue with the stakeholders involved in the implementation of the measures of the Common Agricultural Practice (CAP) so that the recommendations to farmers allow an optimized use of the land

5. Pursue the development of methods that allow the certification of the risk mitigation measures (e.g., for spray drift reducing technologies or seed mixtures), to facilitate the mutual recognition of the tools between countries and organizations, where relevant

6. Facilitate the integration risk mitigation measure into the risk assessment process where possible (i.e., when their effectiveness is quantified)

7. Pursue the development of technical guidance for ecological and environmental monitoring to better generate relevant data, which will measure the effectiveness of risk mitigation measures, and allow

data sharing, extrapolations, and robust databases

8. Pursue the monitoring of pests, diseases, and weeds in farming systems where risk mitigation measures involving non-sprayed zones areas are implemented in order to avoid counterproductive recommendations

9. Pursue the generation of mapping systems such as GIS in support of environmental and ecological modeling tools

10. Pursue the development of ecological and environmental modeling toward tools able to evaluate the effectiveness of risk mitigation measures a priori

11. Develop communication tools, such as the proposed Risk Mitigation Measure Technical Sheets (RMMTS) and declensions in training and stewardship (such as leaflets, applications on mobile devices), to support the transfer of knowledge on the risk mitigation toolbox to farmers and end users

12. Develop networking on the scientific, technical, professional, and legislative and regulatory aspects of the toolbox, to further develop its accuracy and effectiveness

1.6 References

[EC] European Commission. 1991. Council Directive of 15 July 1991 concerning the placing of plant protection products on the market (91 /414 /EEC). Official Journal of the European Union. L 230/1: 19.08.1991.

[EC] European Commission. 1992. Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora. Official Journal of the European Union. L206: 22.7.1992. p. 7.

[EC] European Commission. 2000. Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for community action in the field of water policy. Official Journal of the European Union. L 327/1: 22.12.2000.

[EC] European Commission. 2009a. Regulation (EC) No. 1107/2009 of the European Parliament and of the council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. Official Journal of the European Union. L309: 24.11.2009. p. 1.

[EC] European Commission. 2009b. Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009, establishing a framework for community action to achieve the sustainable use of pesticides. Official Journal of the European Union. L 309: 24.11.2009. p. 71.

[EC] European Commission. 2011. Commission Regulation (EU) No. 547/2011 of 8 June 2011 implementing Regulation (EC) No. 1107/2009 of the European Parliament and of the Council as regards labeling requirements for plant protection products. Official Journal of the European Union. L 155: 11.06.2011. p. 176.

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2 Introduction

Modern agriculture has to deal with the challenge of producing food and fiber of increasing quality for a growing population while meeting improved human and environmental safety standards. Hence, agricultural practices, and among them plant protection products (or pesticides), must meet these standards, which are embedded in the regulatory framework conditioning market entry (EC 1991, 2009a). This regulatory framework requires that every use of each product is evaluated for the possible risks to humans, consumers, and the environment, according to a thorough assessment of the product's properties and dedicated exposure scenarios that reproduce its conditions for use. If necessary, as an outcome of the risk assessment, risk mitigation measures may be required on a use-basis, which aim at reducing exposure to levels that allow this particular use of a product to meet the regulatory safety standards.

Risk mitigation measures are therefore a key component in defining the conditions of use of pesticides in crop protection (EC 2009a, 2011). These measures are specific to the type of risk they intend to mitigate and for example, may consist of a recommendation for special protections for users while handling the product, or to adjust the conditions of use to minimize transfers to groundwater. Regulation (EU) No. 547/2011 provides a list of the typical phrases to be reported on the labeling to implement these risk mitigation measures. For example, the registration regulation for the active substance spinosad dated 2007 recommends that Member States, in their assessment to authorize plant protection products containing the substance, "*pay particular attention to the protection of aquatic organisms; conditions of use shall include risk mitigation measures, where appropriate.*"

Since the implementation of the regulatory framework for the placing of pesticides on the market, the improvement of the sensitivity of the tools and models used, as well as the definition of worst case exposure scenarios has sharpen the screening capacity of risk assessment processes. This has lead to a recommendation to refine risk assessments

and define appropriate risk mitigation measures for an increasing proportion of products. Hence a compilation performed as a preparatory task to the workshop, over the transition period from Directive 91/414/EEC to the new Regulation (EC)No. 1107/2009, concludes that there is a need for risk mitigation for environmental purposes for ca. 95% of the active substances examined at the European level, as shown in Table 2.1:

Table 2.1: Recommendation for risk mitigation measures for the environment as an outcome of the European risk assessment of pesticides. Compilation based on 290 active substances approved, excluding micro-organisms.

Nature of the Risk to be Mitigated	% of Active Substances Concerned
Groundwater	37
Surface water	26
Air	2
Terrestrial vertebrates	29
Non-target arthropods	8
Soil organisms	8
Honey bees	8
Non-target plants	9

The implementation of risk mitigation measures resulted in multiple exchanges between regulatory authorities, where a number of initiatives have been undertaken in order to develop and implement risk mitigation measures and, where possible, take them into account in risk assessment procedures. With these exchanges, networks have been created to further develop risk mitigation tools, as for example in the area of drift reducing nozzles. However, harmonization of the risk mitigation measures implemented among countries is the primary issue, as the measures taken often relate to national policies in first place, as for example in France with the management of spray drift (JORF 2006). National policies also influence the implementation options for risk mitigation measures,

which range from incentive measures, flexible for regulators and usually preferred by farmers, to legal enforcement, less flexible, but perceived as more persuasive and therefore efficient in some countries. Finally, experience shows that the interpretation of a recommendation in a regulatory text and on product labeling varies among farmers, as well as in the regulatory population, and more harmonization or clarity was deemed necessary in the wording associated with risk mitigation tools.

The two workshops described in the Executive Summary discussed the tools for the mitigation of environmental risks, i.e., wildlife, including vertebrates and invertebrates, flora and microorganisms, biodiversity, as well as surface and groundwater quality, as identified as protection goals in the European regulation on pesticides (EC 1991, 2009a). The process followed is summarized in Figure 2.1.

Figure 2.1: Approach followed during the MAgPIE workshops to develop the risk mitigation measure toolbox in the context of Regulation (EC) No. 1107/2009. Details are provided in the text below.

The work was initiated by generating an inventory of the environmental risk mitigation measures in use in European countries. The inventory was compiled from information elicited questionnaires and sent to the participants in preparation of the first workshop. The questionnaires aimed to collect feedback on the risk mitigation tools already

implemented, their legal status (i.e., enforced via a dedicated legislative text, incentives, or as part of good practices), and where relevant, the piece of legislation involved (European, national, or both). Additional questionnaires were also sent during the intermediary period between the two workshops, on the basis of the first inventory, in order to gather further information on the risk mitigation approaches recorded. In total, 11 questionnaires were distributed. We also collected feedback from Member States on the success of implementation of the existing tools. Finally, the consultation covered risk mitigation options in development in each country, as well as the risk mitigation measures considered the most promising.

The inventory of risk mitigation measures was presented and discussed in detail during the first workshop. Discussions were organized around the protection of groundwater, surface water (including the protection of aquatic organisms), the off-crop areas, and the in-crop areas.

In addition, discussions on stewardship actions and on regulatory and legal aspects took place in ad-hoc groups and in interaction with the four subgroups.

For each environmental protection area, the tools were classified into categories based on their nature, i.e., related to products' application conditions, application equipment, or farming practices. The benefits they represented were listed and the corresponding legislation was reported. The tools were then discussed and ranked to reflect their importance as a risk mitigation tool currently or for the future. The ranking was performed using the following criteria:

- Implementation and advancement level: From well implemented tools in countries to tools for which insufficient knowledge or confidence are available
- Regulatory aspects: Regulatory status of the tool, from the straight implementation of established legislation to simple good farming practices; possible regulatory hurdles associated with a tool, as well as options to resolve them
- Economic aspects: Costs
- Ability to measure the efficacy of the tool

- Ability to relate to the risk assessment, i.e., to develop a risk assessment that accounts for the risk mitigation tool quantitatively or qualitatively

On the basis of this analysis, each tool was then allocated into one of the following categories:

1. Not to be promoted
2. Under development
3. Needs consolidation or research
4. Promising tool implemented in some Member States
5. Well established tool implemented in most Member States

The results of this classification, evaluation, and ranking process were used to build the toolbox for the different areas of environmental protection. Detailed technical data on the risk mitigation measures entering the toolbox were gathered during the intervening period between the two workshops. Details on the implementation of risk mitigation measures were requested from Member States through the additional questionnaires. In addition, in order to reach a common understanding on the implementation of the measures, definitions of the terms used were prepared and circulated to participants for comments and adjustments.

Participants reconvened for a second workshop during which they drafted proposals in their respective environmental area and recommendations for the implementation of the measures considered ready for use and for future developments. The options available to measure the effectiveness of the risk mitigation measures were listed for each measure.

A final agreement on the toolbox content and the implementation recommendations were discussed in plenary. In addition, the group discussions aimed to identify measure overlaps and their potential for optimization. In this context, the options for further development of multifunctional field margins were explored, which were based on a dedicated literature review undertaken in the context of the workshop. Overlaps with other regulatory frameworks, including the sustainable use

directive (EC 2009b), the water framework directive (EC 2000), the CAP (EC 2013), or the "Habitat Directive" (EC 1992) were discussed in order to derive proposals for optimization practical to farmers. Transversal aspects, such as aspects relative to the protection of biodiversity, were taken into account by preparing practical recommendations on the risk mitigation measures considered "ready to implement," for which Risk Mitigation Measure Technical Sheets (RMMTS) were drafted. For the most promising tools slated for later implementation, the recommendations were inserted in Technical Advice Sheets. It is important to note that all data and information made available up to March 2015 were included in this analysis.

Finally, participants discussed and drafted the Safety Precaution Phrases as per in Regulation (EU) No. 547/2011, which would support the implementation of the risk mitigation measures listed in the toolbox for further consideration by the European Commission and Member States.

The following chapters summarize the outcome of the workshop and the background information for each of the four subgroups (chapters 4 to 7), as well as for the ad-hoc groups dedicated to legislative aspects (chapter 3), biodiversity (chapter 8), options to measure the effectiveness of risk mitigation measures (chapter 9), and stewardship activity (chapter 10). The proposals amended Safety Precaution Phrases as per Regulation (EU) No. 547/2011 are presented in chapter 3. General conclusions and recommendations are proposed in chapter 11. The RMMTS and Technical Advice Sheets are reported in appendix 1 and supportive information as well as the content of the questionnaires and responses are proposed in all appendices.

2.1 References

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[EC] European Commission. 2013. European Commission, CAP Reform – an explanation of the main elements (MEMO/13/621). Brussels (Belgium): European Commission.

JORF. 2006. Arrêté du 12 septembre 2006 relatif à la mise sur le marché et à l'utilisation des produits visés à l'article L. 253-1 du code rural et de la pêche maritime. NOR: AGRG0601345A. ersion consolidée au 04 mars 2015.

3 Regulatory framework for setting risk mitigation measures under Regulation (EC) No. 1107/2009

Wolfgang Reinert and Martin Streloke

Anne Alix, Burkhard Golla, Gerhard Goerlitz, Volker Laabs, and Veronique Poulsen for the updated set of safety precaution phrases

3.1 Legislative aspects

3.1.1 Regulation (EC) No. 1107/2009 and the placing of plant protection products on the market

Plant protection products (PPP) are recognized as an important tool for producing high quality food in a sufficient amount and at an affordable price. Despite their benefits, their application may also lead to harmful effects on human or animal health or on the environment if the application does not follow the recommended risk mitigation measures (RMM) set out on the label of the applied product. These risk mitigation measures are an important part of Good Agricultural Practice (GAP).

Regulation (EC) No. 1107/2009 defines the legislative framework for the authorization and the placing on the market of PPP in the EU. It is based on the principle of a sequenced pre-marketing authorization: active substances, safeners, and synergists for the use in PPP must be approved at the EU level and placed on a positive list. The PPP themselves are authorized by Member States (MS).

Regulation (EC) No. 1107/2009 reflects the separation of risk assessment and risk management: Approval and authorization are legislative acts based on a scientific assessment of the potential risk from the use of a PPP. Risk assessors and risk managers represent widely separate entities.

According to Article 4(3) of the Regulation, a PPP shall only be authorized

if, among other requirements, it is expected that, consequent to realistic conditions of use, there will be:

- No immediate or delayed harmful effects on human health or animal health or on groundwater
- No unacceptable effects on plants
- No unacceptable effect on the environment, under particular consideration of its fate and distribution as well as its impact on non-target species, biodiversity, and the ecosystem

The term "realistic conditions of use" entails two main elements: good practices (e.g., good agricultural practice, good plant protection practice) and risk mitigation measures.

For reasons of efficiency, risks assessment schemes follow a tiered approach. Products that show no risk under a simple set of generic and very conservative criteria are quickly sorted out as "acceptable" and do not have to undergo a detailed and more sophisticated higher-tier risk assessment. Where the lower-tier risk assessment predicts unacceptable risks, this does not necessarily lead to a non-authorization decision. The use of appropriate risk mitigation measures can result in a reduction in the theoretical risk identified following the application to the GAP towards an acceptable level. Clearly, risk mitigation measures may also be applied subsequently to a higher-tier risk assessment.

Risk mitigation measures are mainly risk management tools. However, as they are part of the risk assessment (in order to prove that a risk identified can be effectively mitigated), Regulation (EC) No. 1107/2009 requires that risk mitigation measures are identified in the draft assessment report (DAR) for a PPP made by the rapporteur Member State (RMS) and addressed in the conclusion on the peer review of an active substance by the European Food Safety Authority (EFSA) (Art. 12[2]), for further adaptation and implementation at national level.

As risk mitigation measures are necessary to assure that a PPP is being used according to the requirements of Article 4(3) (i.e., without harmful or unacceptable effects), they are also part of the authorization of a PPP (Article 31[2]). Risk mitigation measures are displayed on the label of the product (Article 65) and users are obliged to apply them (Article 55);

Member States shall promote high levels of compliance and, where necessary, prosecute and sentence cases of non-obedience (Articles 72, 73).

Article 65 (1) and (3) of Regulation (EC) No. 1107/2009 refers to different types of phrases to be put on the label of a PPP in order to advise the user on any necessary risk mitigation measures:

- Safety provisions are laid down in Directive 1999/45/EC (transitional until 1 June 2015, afterwards phrases from Regulation (EC) No. 1272/2008 apply). These are common for all chemicals falling under the REACH Regulation.
- Safety provisions laid down in Annex III to Regulation (EU) No. 547/2011. These provisions are specific for PPPs and are harmonized (SP-phrases, which are reproduced in Chapter 3.2).
- Any additional specific phrase considered necessary by a Member State to protect human or animal health or the environment. Any such additional phrase must be notified, together with an explanation, to the Commission and all other Member States, in order to consider them for an inclusion into Annex III to Regulation (EU) No. 547/2011.

The zonal system of mutual recognition can only work if risk mitigation measures are harmonized between Member States as far as possible. This does not necessarily mean that all Member States must exclusively use the same set of phrases, but the degree of risk reduction needed should be determined at zonal level and a common understanding of the effectiveness of single risk mitigation measures has to be developed. A classification of measures according to their effectiveness would ease their harmonized use. Article 36(3) explicitly recognizes the role of risk mitigation measures, which address specific needs in a certain Member State. The purpose of risk mitigation measures is mitigating the possible risk of PPPs so, that there is no harmful or unacceptable effect from the use of these products. They must be concrete enough to assure that the protection goal is achieved and flexible enough to allow users to apply the right measures in a practical use situation. Member States shall describe the degree of risk reduction expected when using a specific risk mitigation measure.

3.1.2 The Sustainable Use Directive (SUD)

Directive 2009/128/EC on the sustainable use of PPPs is a piece of legislation that is not dealing with the authorization and placing on the market of PPP, but covers the use phase of these products. It provides measures that are complementary to those foreseen in other areas of EU legislation.

The SUD strives to integrate a high level of protection with the principle of sustainable development (recitals 3, 22, 23). With these objectives, it goes beyond the concept of "no harmful or unacceptable effect," which is the basis for granting authorization and its objectives are the reduction of the impact of PPP use and the promotion of alternatives to conventional phyto-protection practices.

Measures to be taken under this Directive are not related to single products, but follow rather a generic approach to reduce the overall risk and impact of PPP use. Requirements for application machinery, sales of products, or training and licensing of farmers are outlined in this document. Other items like aerial application or use of PPP in specifically protected areas (Water Framework Directive 2000/60/EEC and 2006/118/EC; Biodiversity in Directives 79/409/EEC and 92/43/EEC) are regulated, too. Rules for integrated pest management (IPM) are laid down. A national action plan (NAP) must be implemented by each Member State summarizing all measures to be taken for reducing risks, goals to be reached in a specific period are set, and results must be reported to the European Commission. Ideally, all stakeholders work together to focus their activities and efforts to reach specific goals outlined in the NAP. All these activities must be implemented by the national plant protection acts.

3.1.3 Contribution of industry and farmer organizations

Article 7 of the SUD requires Member States to raise the awareness of the general public about possible risks coming from the use of PPPs. However, as most of the PPPs are applied by professional users, farmers and authorization holders have an important role for the proper implementation of risk mitigation measures. Hence, authorization holders share the responsibility for a safe use of their products. Beside a correct labeling of products, generic awareness-raising campaigns for risks are a

risk mitigation measure, and as such must comply or reflect the conditions of approval and use of products. For example, reducing exposure of surface water from point sources is one such important industry project (see references to TOPPS in Chapter 4 and examples of Stewardship actions in Chapter 10). Specific awareness-raising campaigns for company advisers and users of a specific compound are another tool. Companies can refrain from selling products in vulnerable areas (e.g., groundwater protection). Other examples include stewardship projects for specific PPPs. Model projects (farms) are run by a few companies where, for example, farming practices for improving the status of biodiversity or to reduce runoff are demonstrated.

In a few Member States farmer organizations play an important role in finding effective risk mitigation measures. They are most important in awareness-raising and increasing acceptance among practitioners. More support to farmers and farmer organizations would increase acceptance of risk mitigation measures among regulators and subsequently availability of products on the market. Appropriate risk mitigation measures are an important element to be considered in assessing whether there is a "significant difference in risk" between a candidate for substitution and an alternative product (Annex IV to Regulation [EC] No. 1107/2009).

3.1.4 Other regulatory frameworks

Ideally, the measures taken under different legislations and by authorization holders and farmers are harmonized as far as possible to reduce risks in the most efficient way. Furthermore, acceptance of risk mitigation measures by practitioners should benefit from harmonized approaches under different pieces of legislation. Measures to be taken under Directive 2000/60/EC (WFD) to control erosion can have a direct effect on reducing exposure of surface waters by active substances. The articulation of risk mitigation measures to protect non-target terrestrial life, and especially biodiversity, is more complex. Nature conservation and providing habitats in the agricultural landscape does not fall under regulation (EC) No. 1107/2009, but RMM under this regulation may have unintended consequences for nature conservation and habitat provision. As an example, buffer zones applied to hedgerows as a risk mitigation measure to protect insects may prevent laying out new hedgerow

habitats, even if money from subsidy programs is available. The more habitats there are in a landscape the higher the resilience of communities and populations against any effects of PPPs. In areas where biodiversity is already low, the remaining species are usually not endangered by the use of PPP. However, indirect effects of using pesticides on biodiversity must be avoided. If the use of insecticides leads to an almost complete eradication of insects in an agricultural landscape because only cropped fields are left – in extreme cases only with one crop – no insectivorous birds can live in this area. The use of PPP should not preclude the recolonization of the aforementioned landscapes. Laying out of new habitats to increase the recovery potential and avoid indirect effects on biodiversity or other risk mitigation measures may be needed to avoid indirect effects at least of products posing highest risks. Balancing these issues against the need for efficient food production is a challenge. Joint actions under Regulation (EC) No. 1107/2009, Directive 2009/128/EC (NAPs) together with an intelligent use of subsidy programs are needed to strengthen the carrying capacities of agricultural landscapes.

3.2 Experience from setting risk mitigation measures in Member States

Over the last twenty years, Member States have used mitigation measures to reduce the risk to the environment for several purposes and in different ways. Specific rules for protecting areas of drinking water abstraction, or honey bees and birds, and stipulating buffer zones to surface waters are well established tools and have been widely used for regulatory purposes. Furthermore, new and more specific, tailor-made measures are in use today – for treated seeds or for new groups of organisms, such as terrestrial invertebrates, for example. In addition, risk mitigation measures are needed where new protection goals are being developed, for example in relation to biodiversity, as this has become important over the last few years.

Under Directive 91/414/EEC rules for Member States existed for setting risk mitigation measures. In part, legally binding label phrases were stipulated under national laws to facilitate enforcement of specific restrictions regarded as very important. The product label is the main communication vehicle by which the user is informed of the requirements

for a safe and effective use of a product. The Safety Precautions Phrases (SP-phrases) are among the information that appears on the label, and aim at providing pesticide users with directions for use that effectively mitigate the exposure of and risks to human, animal health, and the environment. These SP-phrases are most often deduced from the conclusions of risk assessments. Details on these risk assessments may be found in guidance documents on the risk assessment, as for example in the EFSA Guidance Document for Birds and Mammals (EFSA 2009), in the SANCO document on terrestrial ecotoxicology (SANCO/10329/2002 rev 2), or guidance documents for non-target arthropods (Candolfi et al. 2002, Alix et al. 2012).

In Annex V of the aforementioned Directive, SP-phrases for protecting the environment were listed and afterwards reproduced in Regulation (EU) No. 547/2011. Table 3.1 reproduces the current SP-phrases with relevance for the protection of the environment, as they may be found in Regulation (EU) No. 547/2011:

Table 3.1: Safety precautions phrases with relevance to the environment as in Regulation (EU) No. 547/2011.

Safety Precaution Phrase	**Criteria for Use of EU 'Safety Precaution' Phrase**
SPe 1: To protect groundwater/soil organisms do not apply this or any other product containing (identify active substance or class of substances, as appropriate) more than (time period or frequency to be specified).	The phrase shall be assigned when an evaluation according to the uniform principles shows that for one or more of the labelled uses such a mitigation measure is necessary.
SPe 2: To protect groundwater/effects on aquatic organisms do not apply to (soil type or situation to be specified) soils.	The phrase may be assigned as a risk-mitigation measure to avoid any potential contamination of groundwater or surface water under vulnerable conditions (e.g. associated to soil type, topography, or for drained soils), if an evaluation according to the uniform principles shows for one or more of the labelled uses that risk-

	mitigation measures are necessary to avoid unacceptable effects.
SPe 3: To protect [aquatic organisms/non-target plants/non-target arthropods/insects] respect an unsprayed buffer zone of (distance to be specified) to [non-agricultural land / surface water bodies].	The phrase shall be assigned to protect non-target arthropods, if an evaluation according to the Uniform Principles shows that, for one or more of the labelled uses, that risk mitigation measures are necessary to avoid unacceptable effects.
SPe 4: To protect [aquatic organisms/non-target plants] do not apply on impermeable surfaces such as asphalt, concrete, cobblestones, railway tracks, and other situations with a high risk of runoff.	Depending on the use pattern of the plant-protection product, Member States may assign the phrase to mitigate the risk of runoff in order to protect aquatic organisms or non-target plants.
SPe 5: To protect birds/wild mammals the product must be entirely incorporated in the soil; ensure that the product is also fully incorporated at the end of rows.	The phrase shall be assigned to plant-protection products, such as granules or pellets, which must be incorporated to protect birds or wild mammals.
SPe 6: To protect birds/wild mammals remove spillages.	The phrase shall be assigned to plant-protection products, such as granules or pellets, to avoid uptake by birds or wild mammals. It is recommended for all solid formulations, which are used undiluted.
SPe 7: Do not apply during bird breeding period.	The phrase shall be assigned when an evaluation according to the uniform principles shows that for one or more of the labelled uses such a mitigation measure is necessary.

SPe 8: Dangerous to bees./To protect bees and other pollinating insects do not apply to crop plants when in flower./Do not use where bees are actively foraging./Remove or cover beehives during application and for (state time) after treatment./ Do not apply when flowering weeds are present./ Remove weeds before flowering./Do not apply before (state time).	The phrase shall be assigned to plant-protection products for which an evaluation according to the uniform principles shows for one or more of the labelled uses that risk-mitigation measures must be applied to protect bees or other pollinating insects. Depending on the use pattern of the plant-protection product, and other relevant national regulatory provisions, Member States may select the appropriate phrasing to mitigate the risk to bees and other pollinating insects and their brood.
SPr 1*: The baits must be securely deposited in a way so as to minimise the risk of consumption by other animals. Secure bait blocks so that they cannot be dragged away by rodents.	To ensure compliance of operators the phrase shall appear prominently on the label, so that misuse is excluded as far as possible.
SPr 2*: Treatment area must be marked during the treatment period. The danger from being poisoned (primary or secondary) by the anticoagulant and the antidote against it shall be mentioned.	The phrase shall appear prominently on the label, so that accidental poisoning is excluded as far as possible.
SPr 3*: Dead rodents must be removed from the treatment area each day during treatment. Do not place in refuse bins or on rubbish tips.	To avoid secondary poisoning of animals the phrase shall be assigned to all rodenticides containing anticoagulants as active substances.

*this phrase applies to rodenticide products.

In spite of this regulatory framework, overall the degree of harmonization

among Member States is low and that may slow down the process of working through zonal applications under Regulation (EC) No. 1107/2009 considerably. Developing harmonized and standardized risk mitigation measures is an important prerequisite to ease zonal authorizations and mutual recognition of registrations allowing one Member State to employ the same risk mitigation measures used by another Member State. A common terminology about all aspects of risk mitigation measures is needed. If there is a need to use different SP-phrases, regulators should be able to judge on the equivalence of different (national) measures. Networks amongst regulators responsible for decision-making on risk mitigation measures should facilitate the process of coming to harmonized approaches.

3.3 A step towards harmonization across Europe

The analysis of the survey undertaken in Europe in the context of this workshop highlighted a need for a toolbox of risk mitigation measures offering Member States a certain degree of flexibility to adjust for their specific conditions on the one hand, while ensuring a common and consistent approach for the whole EU on the other. A common understanding about the effectiveness of single measures – the degree of risk mitigation expected – must be developed to enable harmonized decisions in zonal authorization procedures. The Commission, in close cooperation with Member States, may wish to keep an official list of risk mitigation measures available where the SP-phrase, together with the degree of effectiveness of the measure and effective alternatives, are outlined. If Member States need such alternatives to ease plant protection under their specific conditions they should propose the degree of risk reduction together with a scientific reasoning to the Commission and Member States. Such a list would facilitate the use of modern risk mitigation measures in all Member States while harmonizing plant protection practices at the same time.

Voluntary measures are preferred because acceptance for such restrictions among practitioners is much higher than legally binding requirements. All attempts should be made to increase acceptance. Therefore, it is important to involve representatives of farmer organizations when developing concepts of risk mitigation measures. Easy

to understand text on the label, thorough explanations in training courses, and informational material are important tools when familiarizing farmers with risk mitigation measures. On the other hand, experience has shown that economic pressures reduce acceptance by farmers, especially for any measure leading to loss of soil or area for producing crops or complicating farming practices. Therefore, legally binding risk mitigation measures and a control system are needed to enforce the SP-phrases. Attention must be paid to the enforceability of a risk mitigation measure. The wording must be clear from a legal point of view because in a few situations control actions may end up in court cases.

High quality education and advice for (professional) users is crucial, as an effective implementation of risk mitigation measures is only possible if users are willing to comply. However, no enforcement strategy can go without controls of compliance, as otherwise it will lose its credibility over time. As it is very difficult to control farmers when spraying products it should be possible - for example - to take soil samples in the middle of a field and within the buffer zone. A clear difference of the two soil concentrations may indicate that the label restriction was followed. Other approaches to control the appropriate use of PPP should be developed. It is the responsibility of Member States to decide upon the choice of the most appropriate control methods and whether they are relevant for requirements under the cross compliance system (Regulation (EC) No 1122/2009). Member States must report the results of their controls to the Commission.

In the core assessment of registration reports (RR) it should be clearly stated whether there is a need for risk mitigation for fulfilling the requirements of regulation (EC) No. 1107/2009. Furthermore, the degree of risk mitigation needed should be defined. Participants felt that the exact level of risk reduction needed should not be given, but rather a grouping of risk in classes would facilitate the regulatory work and communication with farmers. Classes of 50, 75, 90 and 95% risk reduction are well established. Also 99% might be an acceptable class if it is scientifically based. Classes may call for a single risk mitigation measure or a combination of different risk mitigation measures; e.g. air-assisted boom sprayer in combination with 90% drift reducing nozzles and end-nozzle.

The reference point or scenario for defining the efficiency of a risk mitigation measure – the degree of risk reduction – should be the same as in the corresponding risk assessment scheme. If runoff PECs are calculated for a field with a length of 100 m the degree of risk reduction should not be determined for one with a length of 10 m. Participants felt that the ongoing use of different exposure models within risk assessments schemes complicates the setting of harmonized risk mitigation measures considerably. Scientific data and a robust scientific reasoning for determining the degree of risk reduction by a single measure is needed, but often complicated by a lack of data and other uncertainties. Furthermore, legal requirements, practicality, acceptance of measures by practitioners, and other non-scientific items are to be considered when setting risk mitigation measures. Therefore, in conclusion, pragmatic approaches need to be found, balancing all important requirements with each other while achieving the legally required safety level.

At least within one zone a common understanding among Member States must be developed regarding the maximum acceptable degree of risk reduction that can be achieved. Otherwise a product or use would be available in one Member State, but not in the other. If a Member State accepts a maximum buffer zone of 100 m to surface waters while another accepts only 20 m, and no other risk mitigation measures are available critical uses can be authorized in the first Member State, but not in the second. For example, in some Mediterranean areas even 500 m could, in principle, be acceptable as there are several crops and uses where no surface waters are around while applying the product.

For all relevant risks (e.g., surface or groundwater, birds and mammals, non-target arthropods, in- and off-crop), exposure routes, and other items, lists can be developed. Such lists might be structured according to the risk reduction class mentioned (e.g., 75%) and, for example, through exposure routes. Member States are free to use and apply the most relevant and suitable measures for their agriculture and conditions. For example, in one Member State spray drift reducing machinery of class 99% is available while in others even 90% is not.

Using class 75% and the exposure of surface waters via runoff as an example, one measure might be a grassed buffer zone of 10 m, and as an

alternative, conservation tillage on the field with a soil cover of 70%. Both measures can be implemented for the same use and reduce the risk respectively. A system of risk reduction points was proposed to ease the use of a combination of risk mitigation measures relevant for the same type of risk and exposure route (for details see Chapter 4.1). For communication with farmers it might be best to use only these points. The label would contain only the information that use of this product in a specific crop requires the use of a "point/class/star two measure" which could for example correspond to a risk reduction class of 75%.

From a compliance and enforcement point of view, risk mitigation measures that are not use- or product-specific, but rather need to be established before sowing the crop and are effective for the whole season should be handled differently. A grassed buffer zone for reducing runoff must be established when, for example, cereals are sown. Such risk mitigation measures may be regarded as crop-specific.

3.4 Set of possible SP-phrases reflecting the toolbox developed during the MAgPIE workshop

There is no need to change the basic regulatory system of setting risk mitigation measures at the EU-level. However, the investigation of SP-phrases relevant for protecting the environment of regulation (EU) No. 547/2011 as illustrated above, has shown that some might be adjusted to give Member States more flexibility in setting appropriate risk mitigation measures. Furthermore, it should be considered whether an EU Guidance Document on setting risk mitigation measures should be worked out in order to describe a clear framework for Member States facilitating the use of EU-wide harmonized label phrases.

It may be difficult to find the text for an SP-phrase describing the risk mitigation measures to reduce a specific risk in a way that can be used effectively in all Member States. Besides language and translational difficulties, agricultural practices are still different, for example the availability of spray drift reducing machinery varies across Member States. The sensitivity of the public towards effects on the environment is different and may lead to different risk management decisions. Therefore, the SP-phrases should allow Member States some flexibility.

Specific parts may be even left open for specifications laid down in official national publications which must be notified to the Commission and other Member States.

During this workshop, participants reviewed existing SP-phrases in order to account for upcoming risk mitigation tools to protect the different compartments of the environment. This lead to the proposal of new and revised SPe- or SPr-phrases, so that they better reflect the diversity of the options offered to users to mitigate risks and improve the clarity of the directions provided.

The following table lists these new or revised phrases as deduced from the expert discussions. Where risk mitigation comprises various options, as for example for the reduction of runoff, it is recommended that risk managers communicate with risk assessors in order to implement the options that better reflect their risk management policy.

Workshop participants conducted an initial review of the phrases during the preparation of these proceedings. The wording proposed in these phrases is meant to reflect the diversity of options while reflecting a harmonized language. The proposed SP-phrases have also been reviewed by representative users and farmers and corrected where necessary for more clarity. They are summarized in Table 3.2 below.

Table 3.2: New and revised SPe- and SPr-phrases as deduced from the risk mitigation measures (RMM) toolbox presented in the MAgPIE proceedings. RMM are allocated into the following categories: Buffer Zones (BZ), aimed at reducing exposure of off-crop areas via spray drift; Field Margins (FM) and Compensation Areas (CA), aimed at providing food sources and habitat to off-crop flora and fauna; Spray Drift Reduction Technologies (SDRT), which involve any technology associated to sprayers, nozzles, or spraying techniques that will reduce the drift; Dust Reduction Technologies (DRT), which involve any technology associated with seed coating, granule manufacture, or drillers to reduce the abrasion of seeds or granules at drilling or to reduce the spread of dust out of the cropped area; Good Agricultural Practices (GAP), which relate to product application (dose and application regime); Crop Management (CM), which relates to agricultural practice in the crop or the field margins aimed at reducing a source of exposure or transfer route; and Bee Management (BM), which relates specifically to measures

applied to managed bees to keep them from exposure.

Environmental Area	Risk Mitigation Measure	Category	Related SPe-Phrase in Regulation (EU) No. 547/2001	Proposed New SPe-Pl in the Context of Regulation (EU) No. 547/2011
Groundwater	Dose of product (reduction/limit) Application frequency (reduction), interval between applications Timing of applications (e.g., overnight; before/after flowering)	GAP	**SPe1**	**Existing phrase – no change:** To protect groundwater/soil organisms do not appl this or any other prod containing (identify ac substance or class of substances, as approp more than (time perio frequency to be specif
Groundwater	Soil type	GAP	**SPe2**	**Existing phrase – no change:** To protect groundwater/aquatic organisms do not appl (soil type or situation specified) soils.
Groundwater/ drainage	Vulnerable areas	GAP	**None**	**New SPe-phrase:** To protect groundwat not apply this or any c product containing (identify active substa or class of substances, appropriate) in vulner areas (areas of drinkir water abstraction or c vulnerable conditions)

Groundwater/ drainage	Crop management tools	GAP	**None**	**New SPe-phrase:** To protect groundwat the use of this or any product containing (identify active substa or class of substances, appropriate) is only allowed if specific management conditio e.g. use of cover crops band application, othe (to be specified) are fulfilled.
Surface water (spray drift) Off-crop	No spray zone Buffer zone of bare soil	BZ	**SPe3**	**Adapted from current SPe3:** SPe3: To protect [aqua organisms/non-target plants/non-target arthropods/ insects] fr spray drift respect an unsprayed buffer zone (distance to be specifi to the edge of the field/surface water bodies]. The edge of t field is either the edge the crop or, in the presence of a margin s the edge of a margin s (see definition in Chap 6).
Surface water (spray drift) Off-crop	Wind direction – dependant on spray zone	BZ	**SPe3**	**Additional text to be added to SPe3:** The buffer zone may b adjusted as a function wind speed, wind direction, and temper conditions based on available recommendations.

Surface water (spray drift) Off-crop	Drift reducing nozzles (incl. adjusted spray pressure, etc.) Special equipment/machinery (Wings-/Tunnel-/Band sprayer etc.) Directed spraying techniques (one-sided spraying, forward-speed, reflection shield, boom-height adjustment etc.)	SDRT	**SPe3**	**Additional text to be added to SPe3:** The buffer zone may b reduced to (distance t specified) if a combina of spray drift reductio technologies such as d reducing nozzles, spec equipment to reduce drift or directed spray technique [is/are] use providing at least (% c drift reduction to be specified).
Surface water (runoff) Off-crop	Vegetated buffer strip	FM	**none**	**In countries where a l runoff risk mitigation measures provided together with an evaluation of their eff (into the form of an official guidance or w book), through e.g., a point-system has bee developed, the follow phrase could be used:** **New SPe X1:** SPe X1: To protect [aq organisms] only apply fields [adjacent/withir to surface water] whe approved mitigation measures(s) with [X% reduction of runoff potential/XY runoff mitigation points] are implemented. The off reference for approve mitigation measures is [detail official referen

				In countries where recommendations regarding the mitigati runoff have been deri from modeling or onl product-specific mitig options are intended, following phrase coul used: **New SPe X2:** To protect [aquatic organisms/surface wa resources] only apply fields [adjacent /withi to surface water] whe the following [measure/measure combinations] were implemented: [detail appropriate measures combinations thereof **Both phrases could be complemented with t following, to take into account the case of farmlands under a rui risk diagnosis prograr where it is available a accepted by regulatoi authorities:** These product-specifi runoff mitigation obligations may be superseded by implementing field-sp runoff mitigation mea on the field/farmland, based on the participa in an officially approve national runoff risk

				diagnosis and manage scheme (detail names officially accepted diagnosis systems). **To tackle the issue of concentrated runoff i agricultural landscape the following phrase i proposed:** **New SPe Y:** To protect [aquatic organisms/surface wa resources] only apply fields [within Y m to surface water] where concentrated runoff is prevented by appropr measures (see [detail official reference or whitebook for concentrated flow mitigation measures]) **This sentence could n the prevention of concentrated runoff r binding in comparison with relying on good agricultural practice c A control in the field would be done via the traces of concentrate runoff in-fields (erosi rills or gullies and deposited sediment a field edges).**
Surface water (spray drift, runoff)	Multifunctional field margins (e.g., as qualification of a vegetated buffer)	FM	**None**	**New SPe to introduce margins to protect on several groups of organisms and mitiga**

Off-crop In-crop	Note that in situations where runoff transfers only need mitigation then SPe2-phrases only would be needed			**transfers via runoff (r functional field margi** To protect [birds/mammals/aqua organisms/non-target arthropods/non-targe plants] and limit risks related to situations o runoff, respect a unsprayed non-croppe vegetated buffer zone (distance to be specifi to [the edge of the fie /surface water bodies which should consist c [wild bird seed mix/wi flower mix/pollen and nectar mix/sown gras order to provide the requested benefits.
Surface water (spray drift,) Off-crop In- crop	Landscape-dependant buffer zones	BZ/CA	**None**	**Additional text to be added to a SPe aimin introducing field mar to protect wildlife:** An implementation of buffer zone for the purpose of wildlife protection may not be needed if recovery are that provide a habitat already present in the farmland and represe (percentage to be specified) of the farml surface.
Surface water (spray drift, runoff, drainage) In-crop	Dose of product (reduction/limit) Application frequency (reduction), interval between applications	GAP	**None**	**New SPe proposing adapted Good Agricul Practices (GAP) to rec exposure of wildlife o transfers via runoff:**

Off-crop	Timing of applications (e.g., overnight; before/after flowering)			To protect [birds/mammals/aqua organisms/pollinators target arthropods/nor target plants/limit risk related to situations o runoff] respect an application rate of maximum (applicatior to be specified)/do no apply this product mo than (time period or frequency to be specif do not apply during th bird breeding period (may be proposed at N level)/restrict applicat to (dates or growth st to be specified).
Birds/wild mammals	Incorporation of granules and pellets	GAP	**SPe5**	**Current SPe5 – no cha** To protect birds/wild mammals the product must be entirely incorporated in the so the end of rows.
Birds /wild mammals	Spillage removal	GAP	**SPe6**	**Current SPe6 – no cha** To protect birds/wild mammals remove spil
Birds /wild mammals	Restriction with regards to the timing of application	GAP	**SPe7**	**Current SPe7 – no cha** Do not apply during bi breeding period (date may be proposed at N level).
Birds/wild mammals	Caution with regards to application of repellents	GAP		**New SPe-phrase:** Add repellents to formulation in order t avoid ingestion by birc

				and mammals.
Birds/wild mammals	Caution with regards to the application of rodenticides	GAP	**SPr1**	**Current SPr1-phrase - change:**The baits mus securely deposited in way so as to minimise risk of consumption b other animals. Secure blocks so that they ca be dragged away by rodents. Apply baits in confine places in order to avoi non-target organisms' exposure.
Birds/wild mammals	Caution with regards to the application of rodenticides	GAP	**SPr2**	**Current SPr2-phrase - change:**Treatment are must be marked durin treatment period. The danger from being poisoned (primary or secondary) by the anticoagulant and the antidote against it shc be mentioned.
Birds/wild mammals	Caution with regards to the application of rodenticides	GAP	**SPr3**	**New SPr3-phrase:** Dead rodents must be removed from the treatment area each c during treatment. Do place in refuse bins or rubbish tips. Remove carcasses in c to avoid secondary poisoning of prey bird carnivorous mammals
Migratory birds	Caution with regards to application	GAP	**none**	**New SPe-phrase:** Do not apply the prod

				on migrant birds resti grounds.
Honey bees Pollinators	Remove or cover bee hive Close hives 1 day before spraying Alert beekeepers	BM	**SPe8**	**Adapted from curren SPe8:** Dangerous to bees./T protect bees and othe pollinating insects do apply to crop plants w in flower./Do not use where bees are active foraging./Remove or beehives during application and for (st time) after treatment. not apply when flowe weeds are present./ D apply before (state tin Respect a flowering st [width to be specified [distance to be specifi of the treated field. Alert beekeepers prio applying the product t allow adequate mitiga measures to be taken, avoid bee colonies' exposure.

3.5 From the toolbox to the implementation of a procedure in Europe

A toolbox or list of risk mitigation measures must be published by the European Commission in close connection with Member States. National orders specifying the measures to be taken in each Member State must be communicated to the Commission and other Member States to facilitate information exchange and subsequent harmonization among Member States. According to Art. 31 (4.a) of Regulation (EC) No. 1107/2009, Member States are still responsible for setting risk mitigation

measures.

To facilitate the implementation of the new type of SP-phrases, these may include a reference to legally binding order that is in force at the Member State-level, in which details of the risk mitigation measure can be stipulated in a way appropriate for each single Member State. As an example for spray drift the following phrase was worked out during the workshop:

SPe3 (new)

To protect [aquatic organisms/non-target plants/non-target arthropods/insects] from spray drift, respect an unsprayed buffer zone of (distance to be specified) to the edge of the [field/surface water bodies]. The edge of the field is either the edge of the crop or, in the presence of a margin strip, the edge of a margin strip.

This new SPe3 can be used for different types of risks, which are mentioned in brackets. Furthermore, the distance to surface waters or hedgerows, or a percentage of risk reduction can be stipulated as appropriate. This new type of SP-phrase would clearly lead to greater harmonization of labels than is currently achievable. At the same, time Member States would be able to meet their responsibilities in a flexible and efficient way.

Another example for runoff is given below:

SPe X1 (new):

To protect [aquatic organisms] only apply to fields [adjacent/within Y m to surface water] where approved mitigation measuress with [X% reduction of runoff potential/XY runoff mitigation points] are implemented. The official reference for approved mitigation measures is [detail official reference].

With this option harmonization is promoted through an agreement on the level of reduction that needs to be reached. Such a system would move the regulatory focus from the measure itself and primarily put it on the protection goal. It has the potential to achieve a high level of harmonization of risk mitigation between different Member States without forcing a break with current national risk mitigation approaches.

There are legal, technical, or historic reasons why things are defined slightly differently, but harmonization can be achieved in future. Geographical and climatic conditions will prevail and flexibility will be needed when all other items are fully harmonized. The new type of SP-phrases would allow to agree on common protection goals in different national contexts.

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4 Risk Mitigation Measures to protect surface waters

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4.1 Introduction

Surface water bodies (e.g., rivers, streams, lakes, ponds) need to be protected from unacceptable impacts of crop protection products. Pesticide pollution sources for surface water can be differentiated into point source and diffuse pollution. Point source pollution originates from farmyard operations and spillages or accidents in the field. Point source pollution is not considered during the regulatory risk assessment for pesticides, as it is not a consequence of a proper use of the products and can be avoided by the operator using appropriate management practices (Good Agricultural Practices). Diffuse pollution can originate from correct pesticide applications to fields. Three major potential pollution pathways exist: spray drift, surface runoff, and (subsurface or artificial) drainage. Another indirect diffuse pollution source for surface water may be recharge from groundwater; however, this pathway is in principle separately addressed via the risk assessment for the groundwater compartment (leaching). Wet or dry deposition of pesticides following volatilization from treated surfaces is a further route of entry to surface waters, but mitigation measures to reduce exposure via this route were not discussed at the MAgPIE workshop.

To protect aquatic organisms against unacceptable threats, the EU regulatory risk assessment process for surface water considers all three major diffuse pollution pathways in its FOCUS (FOrum for the Coordination of pesticide fate models and their Use) scenarios (FOCUS 2001). Six scenarios consider entry via artificial drains and spray drift, while the remaining four consider entry via surface runoff and spray drift.

In principle, each of these pollution pathways may lead to unacceptable predicted environmental concentrations (PECs) in the receiving water body. Consequently, suitable and accepted mitigation measures for each of the three pollution pathways may be needed in EU Member States in order to achieve successful risk mitigation to protect surface waters.

4.2 Surface runoff

Surface water can be contaminated by pesticides dissolved in the water phase of runoff or carried on sediment particles eroded by runoff. Thus, it is necessary to assess the risks for the regulatory authorization of pesticide uses, and for farmers to manage the risks in their fields in practice.

Fundamentally, runoff is caused by precipitation (or irrigation water) not being able to infiltrate through the soil fast enough, resulting in two types of runoff (see Figure 4.1). The first is due to a low permeability at the soil surface (infiltration restriction), due to its natural properties (heavy soil texture, capping), or soil compaction. The second is due to water flow restrictions below the soil surface – because the subsoil is less permeable than the topsoil. This may occur due to natural reasons, such as heavier textured subsoil, or due to soil cultivation practices, e.g., plough pans and sub-surface compaction. However, runoff occurs in these cases only when topsoil in lower slope positions saturates completely with water (saturation excess) due to water movement accumulating there below the soil surface. Another reason for this type of runoff can be the existence of a very shallow groundwater table. In principle, both types of runoff may occur in the same field, though often one will dominate.

Generally, runoff can be subdivided into two groups: one that tends to move uniformly down the whole or part of a field as diffuse sheet runoff, or one that tends to concentrate into discrete flow channels, either due to localized flow restrictions or channelling at the soil surface (e.g., along tramlines, cropping rows) or due to converging water flow in the larger landscape, following so-called talwegs (or waterways) downslope. Any concentrated runoff and erosion channels in-fields effectively extend the river and stream network into agricultural fields and are potentially the greatest cause of adverse diffuse pollution of surface water by pesticides. Through implementing appropriate Best Management Practices (BMPs)

concentrated flow phenomena can be strongly reduced or completely avoided in practice (save for the most extreme precipitation events), thus reducing their potential impact to generally acceptable levels. For example, compaction management of tramlines and orienting tramlines across the slope reduces runoff and erosion from them dramatically (e.g., Deasy et al. 2010). Also, planting grassed waterways in talwegs reduces levels of pesticide in surface water, also acknowledging that pesticides should not be used in these saturated runoff source areas. Concentrated flow is one of the main reasons for cases of low effectiveness of vegetated buffer strips under field conditions (Blanco-Caqui et al. 2006). It can be actively managed through good agricultural practices that also address a range of other environmental issues, primarily soil loss (and hence loss of agricultural productivity), sedimentation of water courses, and nutrient or pesticide transport to surface water.

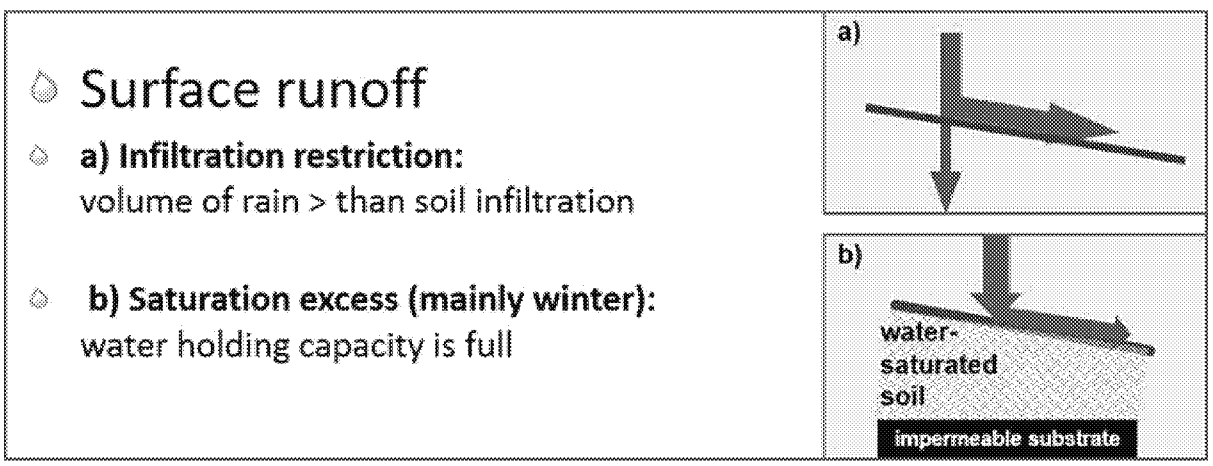

Figure 4.1: Runoff generation types (TOPPS-PROWADIS runoff diagnosis training, www.topps-life.org; modified)

To design a sound regulatory scheme to mitigate risks of runoff, it is important to have insight into how runoff and field erosion affect the amount of pesticide transfered to surface water and how successful buffers are at preventing this transfer. First of all, pesticide transfers from fields are known to increase exponentially as runoff and erosion levels increase. Yet, as the effectiveness of buffers for runoff mitigation is inversely related to the amount of runoff from fields, they generally get more efficient as runoff and erosion levels decrease. This means it is important to have an integrated approach to runoff and erosion management, which combines in-field measures reducing runoff at source (by maximizing water infiltration in agricultural fields), and

vegetated edge-of-field strips, which buffer the remaining runoff from fields. In this way, in-field measures and edge-of-field buffering mitigation strategies act in a synergistic way to reduce runoff from agricultural fields. Consequently, farmers should focus on reducing field runoff (and erosion) at source, using a toolbox of known BMPs, and as a second step implement vegetated filter strips (and additional edge-of-field or off-field measures) to cope with the risk of any remaining runoff and erosion.

From a regulatory perspective, using representative field scenarios, it makes sense first to see how much pesticide transfer from field runoff and erosion needs to be mitigated (% of baseline runoff) to avoid unacceptable effects on aquatic organisms (Art. 4(3)e(ii) of Regulation (EC) No. 1107/2009) in edge-of-field surface water. Afterwards, it would be up to national regulators prescribing measures (or combinations thereof) from a toolbox of different in-field (e.g., no-till), edge-of-field (e.g., vegetated buffer strips), or off-field measures to achieve the targeted mitigation effectiveness. This could either be done via higher-tier modeling, or via a combinatory approach using default mitigation effectiveness values listed for the individual measures in official lists (i.e., national runoff mitigation toolboxes).

In summary, the regulatory perspective tends to work from the water body back to the field, while the farmers' perspective works from the field to the water body. A flexible runoff mitigation concept using a toolbox of acceptable in-field, edge-of-field, and off-field measures brings the two different perspectives together, meeting regulators' needs to ensure environmental protection and farmers' needs for practical ways to implement runoff mitigation measures in their fields while farming productively. Taking into account the variability of rainfall-soil-landscape scenarios and thus runoff generation conditions at catchment level, it is important to note that successful water protection depends on achieving the intended mitigation effectiveness on average across all treated fields in catchments, and less on achieving 100% of the mitigation effectiveness target for each individual field.

Another basic consideration is, if runoff mitigation is only to be implemented for fields directly bordering surface water, or if a certain distance (e.g., 100 m) between downslope field edge and next surface water body will be defined for application of surface runoff risk mitigation

(or at least for concentrated runoff mitigation – see Chapter 4.2.4 on proposed new safety precaution phrases).

4.2.1 Surface runoff risk mitigation concept

The aim of the proposed mitigation concept is to achieve a specified runoff mitigation goal in the field and at the same time to allow farmers a certain degree of freedom to choose the appropriate mitigation measures that fit best to their cropping system and landscape conditions.

Good agricultural practice on fields is a prerequisite for effective runoff risk mitigation; the prevention of concentrated runoff from e.g., tramlines, rills, and gullies is a baseline activity and should be ensured by appropriate best management practices (such as tramline management schemes, grassed waterways, etc.) in any case as far as possible. Existing concentrated flow phenomena will also make many potential runoff mitigation measures less effective or ineffective (e.g., vegetated buffer strips, no-till), prejudicing the intended runoff mitigation effect of implemented measures. Tables A2.1 and A2.2 in Appendix 2 list a number of basic mitigation measures to reduce or prevent concentrated flow in agricultural fields. In the multi-stakeholder EU water protection project TOPPS-PROWADIS (www.topps-life.org), there is also a concentrated flow diagnosis, helping the user to select the appropriate measures to mitigate concentrated flow (Runoff BMP booklet). A more binding option would be to prescribe an effective management of concentrated flow via a safety precaution phrase (see proposal in Chapter 4.2.4 – either for all applied products or only for the ones that require runoff mitigation). For regulatory purposes it is important that a control of measures is possible; this would mean the farmer keeping a plan available for inspection with details of mitigation measures for all fields, together with a scientific reasoning from a competent organization for the effectiveness of the measures. Alternatively, mitigation failure could also be observed in the fields (e.g., erosion rills or deposited sediment below field) and documented.

The base case for diffuse runoff risk mitigation in the EU is the use of FOCUS modeling for different EU runoff scenarios in order to calculate surface water exposure concentrations. If a toxicity-exposure ratio (TER) of a representative (or worst-case) scenario is too low, a higher-tier risk assessment needs to be undertaken to demonstrate a safe use. A similar

approach is taken by EU Member States that have national modeling approaches established for surface water risk mitigation (based on their specific models, parameterization, and scenarios). By defining only a runoff mitigation target (% mitigation needed based on the model and scenario used) in a first step, zonal rapporteur Member States would leave it up to national registration authorities how to achieve this target. At national level, regulators could define their nationally-approved mitigation toolbox, specifying the applicable measures and, if modeling is not used, the assigned default mitigation effectiveness values for their country.

The proposed basic set of runoff risk mitigation measures (toolbox) is listed in Table 5.1 (all pesticides) and Table A2.3 (differentiated according to hydrophobicity of pesticides, thus considering a predominant solution- or particle-based transport of substances) in Appendix 2. It should be noted that such a list (also at national level) needs to reflect the current state of knowledge. Therefore, the lists should be reviewed and updated regularly to remain flexible and open for new mitigation measures and approaches.

The following process is proposed for a harmonized EU regulatory runoff mitigation concept:

Step 1: Identification of basic runoff risk mitigation need (in % of base case)

The risk assessment outcome (EU FOCUS or national) identifies the necessary runoff reduction effectiveness (e.g., a required reduction of the PEC from 10 µg/L to 1 µg/L equals a mitigation need of 90%), which needs to be achieved in practice by implementing appropriate risk mitigation measures.

Step 2: Define appropriate risk mitigation measures (with defined effectiveness) as toolbox

The toolbox is a list of in-field, edge-of-field, and off-field runoff mitigation measures, which are accepted at national level for reducing runoff risks. Depending on national set-up, either the risk mitigation measures are integrated into higher-tier modeling (i.e., measures are considered via modified model parameters, such as reduction in curve number) or a basic mitigation effectiveness value is assigned to each

measure. In Table 4.1, a basic list of runoff mitigation measures and their effectiveness values and integration into modeling is proposed as an EU-wide toolbox.

A basic runoff risk mitigation measure which is already used in several EU Member States (e.g., BE, BG, CZ, DE, ES, FI, IT) and in Switzerland, is the establishment of (permanently) vegetated filter strips between the treated field and surface water bodies. Mostly, filter strips of different widths are accepted (e.g., 5, 6, 10, 20 m) in the regulatory risk assessment, and implementation is easy to control in the field.

Step 3: Provide methodology to calculate overall effectiveness for combinations of risk mitigation measures

As the farmer shall have the flexibility to choose from the toolbox of mitigation measures according to their needs and be able to combine different measures for increased effectiveness, rules must be officially established to dictate (i) which measures may be combined, and (ii) how the overall effectiveness for combinations of measures is calculated.

The use of a simple runoff mitigation effectiveness value per measure (based on evidence from the literature, e.g., choosing a median or x^{th} percentile value of reported results) has the advantage of being easy-to-use and light on regulatory workload; the drawback of this approach is the less accurate approach (ignoring the influence of local environmental conditions) and that a national acceptance for these more simplistic values needs to be ensured.

The effectiveness of vegetated filter strips of different widths, as well as that of several in-field mitigation measures (see Table 4.1), can be modeled e.g., using the PRZM-SWAN-VFSMOD models, meaning that a simulation of overall effectiveness of combinations of measures is also possible. The advantage of the integrated modeling approach is the complete scientific assessment of runoff conditions; the drawback is the higher modeling workload for all integrated measures and intended combinations thereof.

4.2.2 Toolbox of surface runoff risk mitigation measures

There is a multitude of potential and field-tested mitigation measures which can be sorted according to their nature; an overview is provided in

Figure 4.2, which was developed by the TOPPS-PROWADIS project based on a multi-stakeholder process and literature review.

Runoff mitigation measures can be allocated to three different classes: (i) in-field mitigation measures, being implemented on the cropped field; (ii) edge-of-field mitigation measures, being implemented right at the downslope edge of the field; and (iii) off-field mitigation measures, being implemented downslope of the field, but not necessarily in direct contact with the field edge.

A survey of existing regulatory runoff mitigation measures (and related information) in EU Member States and associated countries was conducted in the framework of the MAgPIE workshop. The results are summarized in Table A2.4 in Appendix 2. Results of this survey demonstrate that some of these measures are already used for risk mitigation in one or more EU Member States: e.g., vegetated buffer strips (BE, BG, CZ, DE, ES, FI, IT; also CH), edge-of-field bunds (IT), water retention systems (DE), reduced tillage (BG, IT), band spraying (IT), and soil incorporation of product (IT).

Soil management	• Reduce tillage intensity • Manage tramlines • Prepare rough seedbed • Establish in-field bunds	• Manage surface soil compaction • Manage subsoil compaction • Do contour tilling or disking • Increase organic matter
Cropping practices	• Use Crop rotation • Do strip cropping • Enlarge headlands	• Use annual cover crops • Use perennial cover crops • Double sowing
Vegetative buffers	• Use in-field buffers • Establish talweg buffers • Use riparian buffers • Use edge-of-field buffers	• Manage field access areas • Establish hedges • Establish or maintain woodlands
Retention structures	• Use edge-of-field bunds • Establish vegetated ditches	• Establish artificial wetlands or ponds • Build fascines
Adapted use of pesticides and fertilizer	• Adapt application timing • Optimize seasonal timing	• Adapt product and rate selection
Optimized irrigation	• Adapt irrigation technique	• Optimize irrigation timing and rate

Figure 4.2: Overview of available runoff mitigation measures (source: TOPPS-PROWADIS, Runoff BMP booklet, www.topps-life.org)

In order to propose a toolbox of runoff mitigation measures, a number of

basic mitigation measures were identified during the initial workshop in Rome and in the following break-out group working phase that are considered to be universally accepted as effective in science and by agricultural stakeholders (see Table 4.1). The table lists proposals for basic mitigation effectiveness per measure, based on MAgPIE literature evaluations and expert judgment. These mitigation effectiveness values are designed to express the reduction in pesticide concentrations in surface water in the field that can be expected to arise from deploying the respective mitigation measure. As they are intended for use on the ground in selecting field measures, they deliberately simplify the mitigation effect into a single value. As an example, vegetated filter strips act to reduce pesticide transfer to water via surface runoff by (i) facilitating infiltration of runoff water and dissolved pesticide as it passes across the strip; and (ii) trapping erosive sediment and any associated pesticide. The mitigation effect of a vegetated filter strip will be different for pesticides primarily in the aqueous or sediment phases. For dissolved-phase pesticide, the reduction in pesticide load reaching surface water will be greater than the reduction in pesticide concentration within the surface water because the volume of runoff entering surface water is decreased as well. These detailed processes associated with vegetated filter strips are simplified in Table 4.1 into a single effectiveness value intended to guide selection and uptake of mitigation measures in the field. Considering the different mitigation effectiveness of measures for predominantly solution- or particle-based transport of substances with runoff water, differentiated effectiveness values are supplied in Table A2.3 in Appendix 2 for hydrophilic (Koc <1000 L Kg^{-1}) and hydrophobic pesticides. The values selected are intended to be representative and relatively precautionary, but not absolutely worst-case. It is recognized that field evidence on mitigation effectiveness continues to grow and that values may need to be refined further in due course within the framework of detailed evaluations at Member State and EU level.

Given that the focus of the basic mitigation effectiveness values in Table 4.1 is field selection and uptake of mitigation measures, there is also a need to incorporate the effect of different measures into the risk assessment for pesticides. The final column of Table 4.1 provides recommendations for how to achieve this integration of mitigation measures into regulatory exposure modeling, as an alternative to using basic mitigation effectiveness values.

Further measures, which were discussed but were not considered ready for integration into the basic toolbox of a regulatory concept are listed in Table A2.1 in Appendix 2. At present, these measures do not have sufficiently robust evidence in the available literature, field data, or knowledge, but each may have a role to play in runoff mitigation where a plan can be developed by a competent authority or organization. A comprehensive overview on all discussed measures and also measures to reduce concentrated runoff, the reasoning for their effectiveness, and the literature references are provided in Table A2.2 in Appendix 2.

A specific measure that is reported in the literature, but has not been included in Table 4.1 is vegetated filter strips with width <5m. Although the literature reports such structures to have some effect in reducing pesticide transfer to surface water in runoff, Reichenberger et al. (2007) note in their review that there is systematic bias in the studies present in the literature. Several studies consider vertisols that are prone to cracking and thus macropore flow that may accentuate infiltration of water under dry antecedent moisture conditions. Other studies on narrow buffers used simulated rainfall or run-on, but without pre-irrigation of buffers; the antecedent moisture content is not actually reported in these studies and so the relative vulnerability of the situation studied is unknown. For these reasons, vegetated filter strips <5m in width are excluded from Table 4.1 and research is required to demonstrate the effectiveness of these structures under a wider range of conditions. It should be noted that narrow buffers are likely to be more acceptable to farmers than wider buffers when applied within the field, and that use of in-field buffers to intercept runoff close to the point at which it is generated is a particularly effective approach in many situations. Ultimately, it remains up to the individual Member States to define the minimum width of vegetated buffer strips that they still consider to be of reliable effectiveness for runoff mitigation under their national conditions.

Table 4.1: Proposed toolbox of basic runoff mitigation measures. The basic mitigation effectiveness provides a generic and representative measure of reduction in pesticide concentrations in surface water that aims to simplify and promote selection and uptake of mitigation measures in the field. The proposed modeling approach provides a recommended method to incorporate the respective mitigation measure into regulatory exposure modelingrisk assessment. More detailed

information on references is provided in Table A2.2 in Appendix 2).

Runoff Mitigation Measure	Strength of Scientific Evidence*	Basic Mitigation Effectiveness[1]	Proposed Modeling Tools or Parameter Modifications
Edge-of-field measures			
5 m vegetated filter strip	+++	40%[2]	VFSMOD[14]
10 m vegetated filter strip	+++	65%[3]	VFSMOD
20 m vegetated filter strip	+++	80%[3]	VFSMOD
Edge-of-field bunds	+	40%[4]	Calculation of water retention, infiltration and environmental fate
In-field measures			
No-till / reduced tillage	++	50%[5, 6, 7, 8]	Curve number reduction: -3
In-field bunds (row crops)	+	50%[4]	Curve number reduction: -3[15]
5 m vegetated filter strips	++	50%[9]	Modeling approaches would need to be adapted
Inter-row vegetated strips (in permanent crops)	++	50%[2,4]	Proportionate consideration of curve numbers[16]
Off-field measures			
Artificial wetland	+++	75%[10, 11]	Calculation of water retention,

and retention pond			infiltration and environmental fate
Vegetated ditches	++	50%[12, 13]	Calculation of water retention, infiltration and environmental fate

* Symbols mean: +: few scientific publications existing; ++: many scientific publications existing; +++: abundant scientific publications existing; see also Table A2.2 in Appendix 2.

[1] Values give broad effectiveness (expressed in % of baseline concentration in surface water due to surface runoff) based on MAgPIE literature evaluations and expert judgement; values may need to be refined further to reflect more detailed evaluations of efficacy at Member State and EU level; these values are used to derive mitigation points for each measure from respective mitigation point scale (see Table 4.2).

[2] CCPF-Ministero della Salute 2009

[3] Conservative mean of values for high- and low-sorbing pesticides from: (Reichenberger et al. 2007).

[4] Proposal of Swiss regulatory authority for runoff mitigation effectiveness: 50%; according to reference 2: 20%.

[5] UBA 2004

[6] Miao et al. 2004

[7] Deasy et al. 2010

[8] Maetens et al. 2012

[9] Reichenberger et al. 2007. See Fig. 1, and reflecting the fact that buffer strips closer to runoff source have higher efficiency than edge-of-field or riparian buffer strips.

[10] Stehle et al. 2011

[11] Maillard et al. 2012

[12] Gregoire et al. 2009.

[13] Moore et al. 2008.

[14] The regulatory status of VFSMOD in the EU regulatory process is currently uncertain. The model is recommended for use here given its general validation status in the scientific literature and because it is able to reflect changes in buffer efficacy based on e.g. changes in antecedent moisture conditions. Additional work is recommended outside of the MAgPIE process to reach a conclusion on the regulatory acceptability of the model in the EU. A particular issue is evaluation of coupling of the basic VFSMOD code with the regression equation for pesticide transfer across vegetated filter strips reported by Sabbagh et al. (2009).

[15] Bunds are equivalent to terraces: Using the TR-55 curve number (CN) guideline, up to 4 lower CN are recommended; Use a fraction, if the bund only catches part of the runoff (bypassed)

[16] Proportionate calculation means: curve number CN= (% permanent crop area * CN(permanent crop)) + (% vegetated strip * CN(vegetated strip))

In order to achieve an adequate mitigation effectiveness of measures, appropriate environmental conditions and technical aspects of their implementation need to be defined in detail (at national level), as well as

– if needed – appropriate activities for maintenance of measures. The technical advice sheets for risk mitigation measures in Appendix 1 provide a first basis for such specifications at an integrated European level.

The basic runoff mitigation effectiveness values provided in Table 4.1 are proposals for average effectiveness (e.g., usually 25th to <50th percentile), derived from available literature data and completed based on expert judgement. The reason for not using a "worst case" approach (e.g., 10th percentile) for measure effectiveness is (i) that an appropriate definition of acceptable implementation conditions (e.g., prohibiting establishment of vegetated filter strips in shallow groundwater areas) and maintenance prevents many cases of low effectiveness (as reported in the literature), and (ii) that the mitigation measures need to achieve their assumed effectiveness on average in an agricultural landscape, thereby making a certain amount of cases with lower effectiveness acceptable. The effectiveness of some measures depends on the sorptive properties of active substances (i.e., high or low Koc), which is reflected in differentiated effectiveness values provided as an alternative in Table A2.3 in Appendix 2.

Obviously, EU Member States should be free to include or discard measures in their national toolbox and to assign different effectiveness values to each measure (reflecting the degree of conservativeness for each measure). This does not prejudice the goal of a harmonized (zonal) runoff mitigation concept, as long as a certain minimum degree of overall runoff mitigation (e.g., 90%) is still possible in each EU Member State.

Control of the appropriate implementation of regulatory risk mitigation measures must be possible in the field. For some (perennial) risk mitigation measures this is straightforward (e.g. via field inspection), while for others an adequate mechanism for documentation (e.g., field-specific records, including photographs) by the farmer, as well as auditable criteria for "good implementation practice" need to be defined and published.

4.2.3 Calculating overall mitigation effectiveness for combinations of measures

All risk mitigation measures that can be integrated into regulatory modeling can also be simulated in combinations, providing a direct

mitigation effectiveness output for combinations of measures.

For measures that have been assigned a basic mitigation effectiveness value (e.g., 50% runoff reduction), a methodology must be established to calculate the overall mitigation effectiveness for two or more measures applied to one field. In principle, two standard methods can be used to calculate the overall mitigation effectiveness of combinations of risk mitigation measures: a multiplicative or an additive approach. As a compromise between the relatively less conservative (additive, or linear) and the most conservative (multiplicative, or logarithmic) approach, a hybrid approach may be adopted, providing intermediate protectiveness (see Table 4.2 and Figure 5.3).

In order to provide a simple user interface for farmers and advisors, risk mitigation effectiveness for each measure could be translated into mitigation effectiveness points (e.g., 50% risk reduction equals 30 points, 90% risk reduction equals 100 points, for the multiplicative approach). The farmer just needs to know the number of mitigation points that is required for a product use and can then choose a combination of measures from an official list of measures (whitebook) that adds up to equal or more than the defined points requirement. The whitebook is to be established at national level and lists the acceptable runoff mitigation measures and the mitigation points per measure. As the point scale used reflects the combinatory approach (multiplicative, hybrid, additive), the farmer can always simply sum up the points without having to deal with complicated calculations. In principle, this points system could be applied to all surface water exposure pathways, i.e., also drainage and spray drift.

Table 4.2: Overview on potential combinatory point system scales for calculation of mitigation points.

Mitigation Effectiveness (%)	**Calculated Mitigation Points**		
	Logarithmic scale: Multiplicative effects (most conservative)	Double-exponential scale: Hybrid effects (medium conservative)	Linear scale: Additive effects (less conservative)
40	22	21	20

45	26	25	25
50	30	30	30
55	35	34	35
60	40	39	40
65	46	44	45
70	52	50	50
75	60	56	55
80	70	64	60
85	82	73	65
90	100	86	70
95	130	106	75
99	200	130	79

As can be seen in Table 4.2 and Figure 4.3, there are no large differences in the scale system below a mitigation requirement of 70%; the conservativeness of the different methods shows only for higher mitigation needs. Yet, all of these approaches ignore the potential for synergistic effects of mitigation measures, reflecting their basic conservativeness: in reality, for example, the reduction of runoff water by 50% using no-till would further increase the runoff reduction effectiveness for vegetated filter strips, as they show higher effectiveness for lower runoff water volumes.

EU Member States might want to define an upper limit for possible mitigation to be achieved (e.g., 99%, as in Table 4.2), thereby creating a practical cut-off for products with high mitigation needs. Similarly, Member States may (i) limit the maximum width of vegetated filter strips that they are willing to accept in their regulatory risk mitigation systems

or (ii) define a minimum width of vegetated filter strip (e.g., 5 m) that always needs to be established as a basic measure if runoff mitigation is needed.

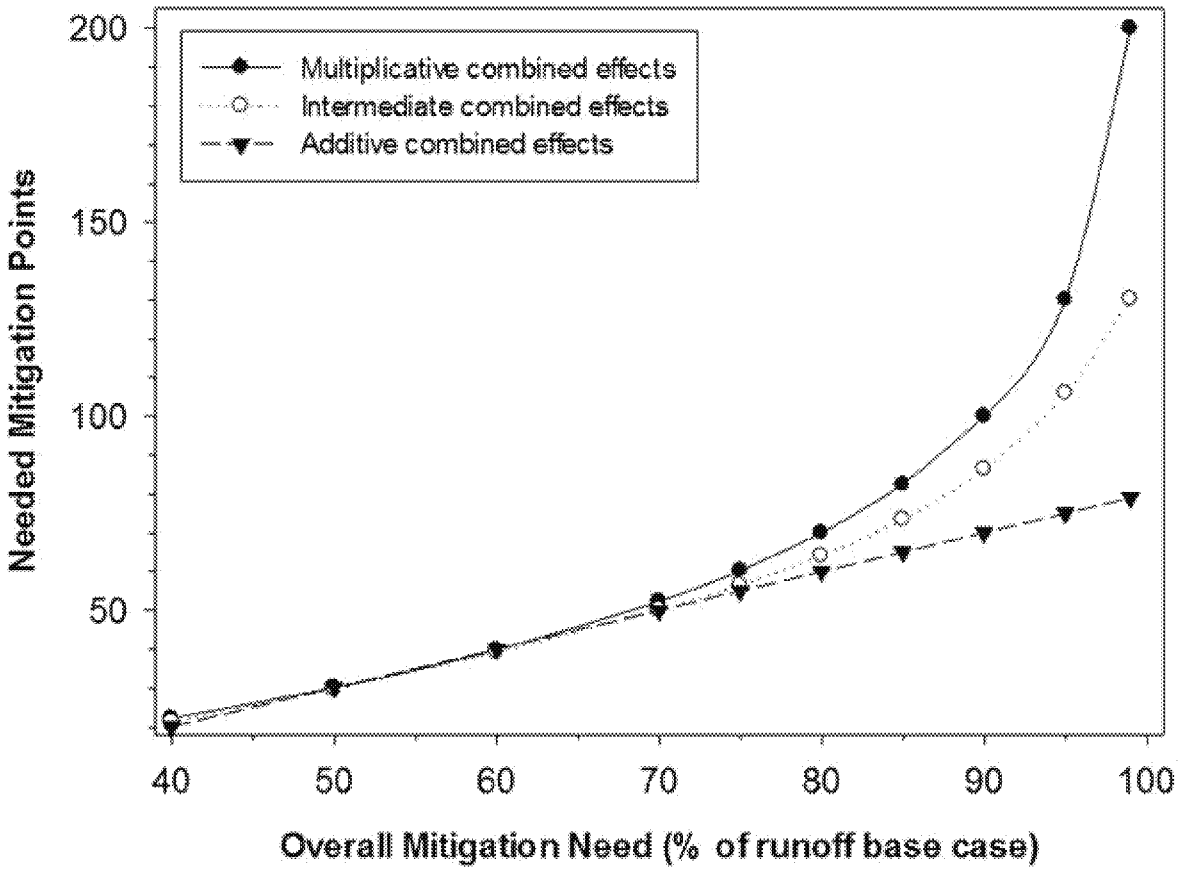

Figure 4.3: Visualization of mitigation points assigned to the overall mitigation need.

Mitigation case example using field evidence-based effectiveness values for measures:

Step 1: Determination of basic runoff mitigation need

Product A needs a reduction of the runoff-induced exposure by 90%. This would translate to
- 100 mitigation points (Table 4.2, logarithmic scale)
- 86 mitigation points (Table 4.2, double-exponential scale)
- 70 mitigation points (Table 4.2, linear scale)

Step 2: Toolbox of measures

The amount of mitigation points per measure is determined in this example by taking the individual mitigation effectiveness value (%) listed

in Table 4.1 and reading across the corresponding mitigation points in the different point scale systems (in practice, an official list of measures would only provide the mitigation points per measure). For example, a 10-m vegetated buffer strip is listed with an effectiveness of 65% (Table 4.1), which corresponds to 46 mitigation points in the logarithmic scale, 44 in the hybrid scale, and 45 in the additive scale in Table 4.2.

The farmer checks the available mitigation measures in the official table (e.g., the ones from Table 4.1), which would also list the mitigation points per measure, and can now choose different measures or combinations thereof. Presumably, the farmer will choose the measure(s) that are implemented with the least influence on their cropping system or the least investment regarding time and money (or land) for establishment and maintenance.

Step 3: Assessment of combinatory effects

The farmer adds up the points for the chosen measures and checks if this achieves the necessary amount of mitigation points needed for the application of the product. For this example, the following combinations of measures would qualify:

Logarithmic (multiplicative) scale (100 points needed): e.g.,
→ 20 m vegetated filter strip (70 points) & no-till (30 points): 100 pts
→ 10 m vegetated filter strip (46 points) & no-till (30 points) & vegetated ditch (30 points): 106 pts
→ 5 m vegetated filter strip (22 points) & no-till (30 points) & retention pond (60 points): 112 pts

Double-exponential (hybrid) scale (86 points needed), e.g.,
→ 20 m vegetated filter strip (64 points) & no-till (30 points): 94 pts
→ 5 m in-field vegetated filter strip (30 points) & no-till (30 points) & vegetated ditch (30 points): 90 pts
→ no-till (30 points) & retention pond (56 points): 86 pts

Linear (additive) scale (70 points needed), e.g.,
→ 10 m vegetated filter strip (45 points) & no till (30 points): 75 pts
→ 5 m vegetated filter strip (20 points) & retention pond (55 points): 75 pts
→ 5 m vegetated filter strip (20 points) & no-till (30 points) & vegetated ditch (30 points): 80 pts

Mitigation case example using higher-tier modeling to assess overall mitigation effectiveness

The modeling is done using the appropriate substance parameters, as well as the chosen runoff scenario parameters, based on the (national) risk assessment scheme. An indicative example of the approach that could be taken is provided below. The active substance has the following use conditions and properties:

Use conditions: on maize, applied to soil at 1.0 kg a.s./ha; target date: between 1 April and 1 May.
Physico-chemical propertiesof active ingredient:
- molecular weight 300 g/mol
- water solubility 100 mg/L
- vapour pressure 1 x 10^{-7} Pa
- soil sorption: Koc 100 L/kg, nf 0.9
- soil degradation half-life (at 20°C): 30 d
- water-sediment degradation half-life: 30 d
- degradation half-life on plant surfaces: 10 d

Regulatory acceptable concentration(RAC) in surface water: 7 µg/L

Step 1: Calculation of the basic runoff risk for surface water

Standard FOCUS step 3 modeling is done based on the data above. The risk assessment fails at this step, as the PECmax is determined at 41.4 µg/L in the R4 stream scenario (Table 4.3); for comparison purposes, in order to achieve the RAC this would translate into an 83% mitigation requirement.

Step 2: Integration of toolbox measures into higher tier modeling

Step 4 modeling is carried out using SWAN to include VFSMOD simulations of the effect of a vegetated filter strip (VFS). This demonstrates that e.g., a 20-m VFS provides the necessary mitigation in all four FOCUS scenarios (PECmax of 5.15 µg/L in the R3 stream scenario), complying with the regulatory acceptable concentration (Table 4.3).

The effect of a minimum tillage mitigation is simulated by re-running standard FOCUS modeling, but with all runoff curve numbers reduced by

3. However, the use of minimum tillage alone does not meet the regulatory acceptable concentration (PECmax of 39.1 µg/L in the R4 stream scenario).

Step 3: Assessing the overall effectiveness for different combinations of mitigation measures

The final modeling step investigates potential combination of runoff risk mitigation measures, for example to allow a reduction in width of the VFS. For instance, a combination of minimum tillage with a 10-m VFS provides the necessary mitigation in all four FOCUS scenarios (PECmax of 6.28 µg/L in the R3 stream scenario).

The modeled regulatory surface water concentrations are summarised for all scenarios and mitigation options in Table 4.3.

Table 4.3: Modeled surface water concentrations using different modeling tiers for mitigation case example

Modeling Step	**FOCUS Scenario**				
	R1 pond	R1 stream	R2 stream	R3 stream	R4 stream
FOCUS Step 3	0.33	16.7	15.3	31.2	**41.4 failed**
Step 4: 20-m VFS	0.09	0.42	0.56	**5.15 ok**	0.42
Step 4: minimum tillage*	0.21	3.62	12.1	17.2	**39.1 failed**
Step 4: min-till + 10-m VFS	0.14	0.81	1.07	**6.28 ok**	0.08

*Note: effectiveness of the VFS is mainly determined by the volume of runoff water leaving the field. Although minimum-tillage has a relatively small effect on the concentration of the pesticide in runoff, it reduces the volume of runoff to a greater extent. Thus a smaller VFS is required to achieve the same net mitigation.

If a modeling approach is used, the product label would need to specify which measures or combinations of measures are required for an acceptable application of this product to a field.

In principle, modeling and field-evidence approaches can also be combined, e.g., by deriving single or overall mitigation effectiveness values from modeled measures or combinations thereof (% mitigation

achieved) and then continuing the process as described for the field-evidence based approach for combinations with measures for which no integration into models was achieved.

4.2.4 Resulting label language

The current Safety Precaution phrases according to Regulation (EU) No. 547/2011 (see Chapter 3) do not yet allow to translate a flexible runoff mitigation concept into legal label language. Therefore, the following new SP-phrases are proposed, which are compatible with a flexible toolbox approach to mitigate diffuse runoff:

SPe X1: To protect [aquatic organisms] only apply to fields [adjacent/within Y m to surface water] where approved mitigation measures(s) with [X% reduction of runoff potential/XY runoff mitigation points] are implemented. The official reference for approved mitigation measures is [detail official reference].

The official document, detailing the list of accepted mitigation measures and advice for their implementation and maintenance, needs to be established at national level.

Alternatively, for modeling approaches with specified (combinations of) measures:

SPe X2: To protect [aquatic organisms] only apply to fields [adjacent / within Y m to surface water] where the following [measure / measure combinations] to mitigate runoff are implemented: [detail the list of appropriate measures or combinations thereof].

In practice, farmers will need to determine for each field the maximum runoff mitigation effectiveness needed for the complete group of pesticides (planned to be) used on that field with a given crop rotation. That said, many runoff mitigation measures are perennial (e.g., vegetated filter strips) and cannot or should not be established or dismantled each year.

The selection of mitigation measures by farmers and their implementation would need to be documented for each field, so that an effective control is possible. The official list of accepted mitigation measures will need to detail the correct establishment and maintenance

procedures for each measure, together with auditable criteria for adequate measure implementation.

In addition, the new SP-phrases may be complemented by the following sentence for certain products or mitigation effectiveness levels:

These product-specific runoff mitigation obligations may be superseded by implementing field-specific runoff mitigation measures on the field orfarmland, based on the participation in an officially approved national runoff risk diagnosis and management scheme ([detail names of officially accepted diagnosis systems]).

This phrase would enable farmers to switch from product-specific runoff mitigation measures to (officially approved) field-specific runoff risk mitigation (e.g., Aquavallee® diagnosis by Arvalis Institut de Végétal in France, TOPPS-PROWADIS runoff diagnosis scheme), allowing them to achieve equivalent effectiveness but at lower cost. The logic behind this approach is that a field-specific approach would prevent runoff from fields (regardless of products used), using mitigation measures adapted to the specific pedo-climatic and landscape properties.

To tackle the issue of concentrated runoff in agricultural landscapes, the following phrase is proposed:

SPe Y: To protect [aquatic organisms] only apply to fields [within Y m to surface water] where concentrated runoff is prevented by appropriate measures (see [detail official reference for concentrated flow mitigation measures]).

This sentence could make the prevention of concentrated runoff more binding in comparison with relying on “good agricultural practice” only. As for diffuse runoff measures, the choice of mitigation measure(s) by farmers and their implementation would need to be documented for each field, so that an effective control is possible. The official list of accepted mitigation measures will need to detail the correct establishment and maintenance procedures for each measure, together with auditable criteria for adequate implementation of measures. Alternatively, a negative control in the field could be achieved via a diagnosis and documentation of traces of concentrated runoff in fields (erosion rills or gullies and deposited sediment at field edges).

4.3 Spray drift

Spray drift assessments are typical mandatory features of regulatory evaluations of plant protection products at the European level (Annex I assessments), zonal level, and on a country authorization basis. The purpose of this section is to provide a summary of:

- How spray drift is characterized
- What spray drift profiles are used to support regulatory risk assessments
- National options for mitigating spray drift
- Interpretation of labels under usage conditions

Particular emphasis is placed on two specific mitigation strategies: no spray zones and use of spray drift reduction technology. These techniques are also mentioned in Chapter 6, together with other mitigation options to be considered in an off-crop mitigation context. This chapter presents technical and regulatory context surrounding no spray zones and spray drift reduction technologies, which is considered warranted simply because there are sometimes significant differences between Member States when considering:

- Technical drift characterization and representation
- Permissible ranges of no-spray zones for different crops
- Acceptance of spray drift reduction technology as a label mitigation option
- Where accepted, the permissible options of spray drift reduction technology
- Examples where only voluntary implementation is permitted
- Examples of flexible implementation with adaptation of mitigation taking into account local conditions

A brief discussion on the implementation of spray drift reduction technology is proposed, recognizing that in a number of Member States

there remain regulatory barriers for adoption or other constraints with users that may limit effective implementation. Possible options to address this are discussed. An illustration of expansion of options with spray drift reduction technology as a flexible strategy for implementation of spray drift mitigation is also provided based upon experiences in Southern Europe. Finally, proposals and recommendations for more practical, flexible, and meaningful spray drift mitigation (and spray drift reduction technology, in particular) are discussed with a view towards more effective harmonization of policy on spray drift mitigation between Member States.

4.3.1 How spray drift is characterized

Spray drift measurements may be performed under reference conditions in the field to assess the amount of applied spray volume blown away downwind of a treated area and deposited on the soil surface next to the treated field. This may be facilitated through the use of a fluorescent tracer to quantify spray deposition. A non-ionic surfactant may be added to mimic a spray solution of a plant protection product. Spray drift deposition is then assessed at a range of distances relative to the edge of the treated zone. Studies may be conducted with a range of different reference conditions (wind speed, nozzle height, temperature, humidity, etc.). Consequently, differences arise between assessments related to the choice of standard reference conditions for tests. This is illustrated in Table 4.4 (Huijsmans and van de Zande 2011).

Table 4.4: Summary of boom sprayer reference conditions (after Huijsmans and van de Zande 2011)

	NL	DE	UK	FR	PL	BE	SE
Nozzle	XR11004	FF 03, 04[a]	FF110/1.2/3.0	FF11002	FF03	FF03	F, M, C
Spray pressure (bar)	3	2.0-5.0	3.0	2.5	-	3	-
Spray volume (l/ha)	300	150-300	Speed dependent	-	-	-	-
Sprayer speed (km/h)	6.5	6-8	6-12 (12, 16)[b]	8.0	-	-	7.2
Boom height (m)	0.50	0.50	0.5 (0.7, 1.0) [b]	0.70	0.5	0.5	0.25, 0.40, 0.60

Sprayed surface	Potato, bare soil	Bare soil, short grass	Short grass, crop	-	-	-	Short grass
Crop height (m)	0.5 / 0.10	0.10	0.05 – 2.0	-	-	-	-
Sprayed width (m)	24	20	48	-	-	-	96
Temperature range (°C)	5-25	10-25	-	-	-	-	10, 15, 20
Wind speed range (m/s)	1.5-5.0	1-5	2.5 (2.5, 3.5)[b]	-	-	-	3,0, 4.5
Wind speed height (m)	2.0	2.0	3	-	-	-	2.0

[a] Basic drift curve contains data from measurements from other flat fan (FF) nozzle types and sizes

[b] Values in parenthesis are recently proposed (not yet adopted) for bystander/residents assessments

With respect to spray drift reduction technology, ISO identifies six classes of drift reducing technologies (ISO 22369-1, 2006) relating respectively to 25, 50, 75, 90, 95, and 99% of drift reduction. The underpinning characterization of drift reduction effectiveness varies and may include full-scale field trials (ISO 22866), wind tunnel tests (ISO 22856), and droplet size characterization (ISO/DIS 25358).

During discussions at the second workshop it was agreed that these differences should be acknowledged, but that harmonization of testing standards beyond ISO 22369 would be more effectively addressed independently via spray physics expert working groups. It was agreed that the workshop delegates should focus on general principles of mitigation – what is used, how it is used, and what opportunities can widen options and build upon regulatory and technical experience.

4.3.2 What spray drift profiles are used to support regulatory risk assessments

In general, the most common basis for representation of spray drift in risk assessments is drift tables presented by Rautmann et al. (2001). This, in turn drew upon the fundation of spray drift data tables established by Ganzelmeier et al. (1995) derived from trials over bare ground and were considered at the time to represent a worst case scenario. The original datset was collected from the late 1980s to the early 1990s, and included

a total of 119 trials comprising 16 drift trials for field crops, 21 trials for grape vines, 61 trials for fruit crops, and 21 trials for hops. The 90th percentile values (or overall 90th percentile for multiple applications) derived from the data have remained the mainstay of EU risk assessments ever since (including incorporation into the FOCUS Surface Water modeling framework (FOCUS 2001). There are, however, notable differences in regulatory strategy and these are summarized in Figure 4.4 and detailed below.

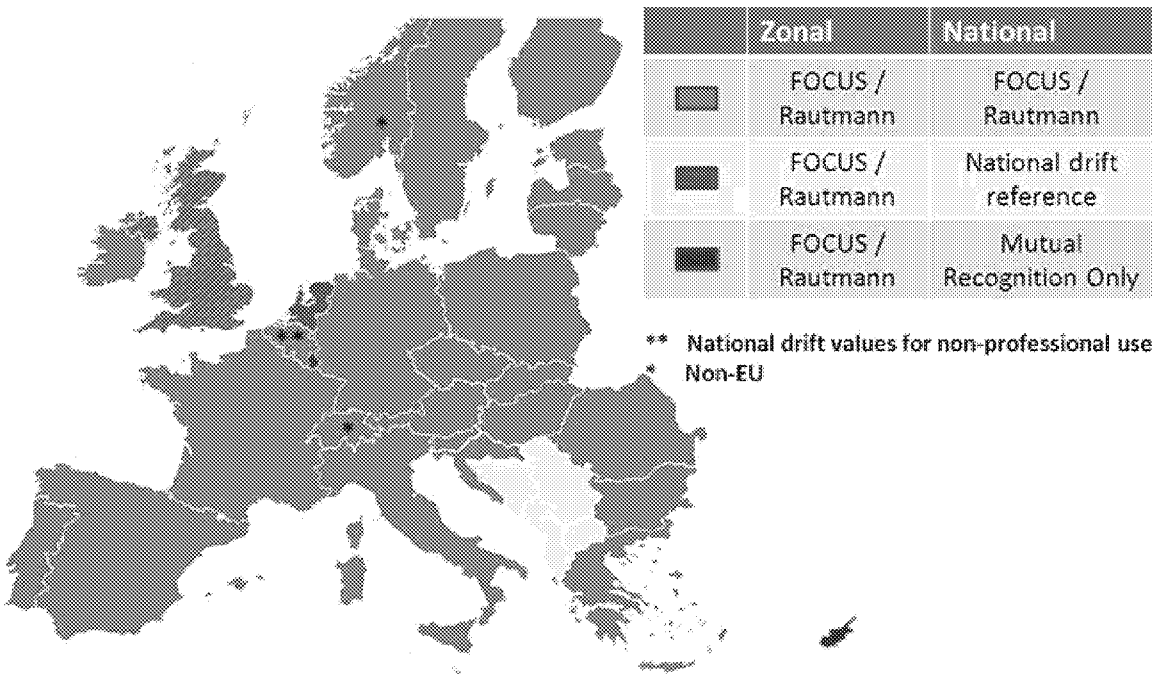

Figure 4.4: Summary of regulatory preferences for drift representation

Two Member States (the Netherlands and the UK) employ spray drift representations that differ from Rautmann et al. (2001) and these are discussed in brief below.

Netherlands

In the Dutch assessment procedure different spray drift curves are used for arable crops (boom sprayers), fruit crops, and nursery trees, all originating from field measurements carried out in the Netherlands based upon reference standards summarized (Huijsmans et al. 1997) in Table 4.4 for boom sprayers. In the Netherlands, the standard reference basis for assessment includes spray of a potato crop and in the near future also for bare soil or small crops (i.e., grass). For boom sprayers, the Netherlands specifies the position of the last nozzle relative to the last

crop row. This originates from the experience in measuring spray drift in a crop situation where the nozzle position above the last crop row is fixed while the edge of the canopy varies. In other drift frameworks used in other countries, the edge of field is defined as half a nozzle spacing distance from the last nozzle (ISO 22866 2005). On this basis, and because of differences in reference nozzle standards and wind speed conditions during spray drift measurements, spray drift potential for the Netherlands is higher than represented in FOCUS.

Dutch spray drift profiles are implemented as a component of the Dutch government's policy (Multi-Year Crop Protection, Water Pollution Act, Plant Protection and Biocide Act, Sustainable Crop Protection I and II; LNV 2004, EZ 2013) that has set goals for the reduction of the emission of pesticides into the environment. A minimum set of agreed measures are mandatory to reduce spray drift deposition in practice based on drift-reducing application techniques and crop-free buffer zones based on the Water Pollution Act (I&M 2012). For example, in arable field crop spraying it is mandatory to use nozzles with at least 50% drift reduction on the outside 14 m of the field (VW and LNV 2001), a maximum boom height of 0.50 m and an end-nozzle on boom sprayers spraying alongside waterways (I&M 2012). For frequently sprayed crops like potatoes, flower bulbs, and onions, a crop-free buffer zone of 1.5 m measured between the center of the last crop row and the start of the ditch bank is obligatory. On the field edge it is also allowed to grow another non-sprayed crop or vegetation to serve as a buffer zone thereby introducing a no spray buffer zone. With higher level spray drift reducing techniques (drift reduction of 50% up to a drift reduction of 95%) the crop-free buffer zone is allowed to be smaller, up to 0.50 m (TC 2014) as long as authorization thresholds of pesticides are not exceeded for surface water (Ctgb 2014). For orchard spraying, specific combinations of spray techniques (Van de Zande et al. 2012) and crop-free buffer zones are mandatory as a first level leading to a minimal drift reduction of 90% at the water surface. Regulations are embedded in both the Pesticide Act and the Water Pollution Act. Based on the spray drift deposition level in surface water, the width of crop-free buffer zones can be set and impacts on the registration process of agrochemicals determined. A general reduction in spray drift to surface water next to the sprayed field can be achieved by improvements in spray application techniques. So in general in the Netherlands there are two levels of implementing SDRT and buffer

zones:

1. Protection by general rules of mandatory drift reducing technologies and crop-free buffer zones

2. Wider buffer zones or more drift reducing technologies based on the toxicity of the agrochemical in the authorization procedure. From 2015 onward a minimum drift reduction of 75% is to be used on all fields sprayed with agrochemical irrespective of whether the field is alongside a water course.

United Kingdom

The current UK accepted approach for calculation of PECsw by spray drift is described in a previous Aquatic Guidance document (SANCO/3268/2001) drawing upon drift profiles proposed by Rautmann et al. (2001). This remains the primary basis for evaluation in most cases.

However, the UK authorities (CRD) have recently revised their policy to allow for greater flexibility to consider horizontal boom spray drift reduction technology. In this scheme, uses or products that do not give a satisfactory risk assessment without reliance upon SDRT can be assessed assuming the use of LERAP three star nozzles (HSE 2014), which provide at least 75% drift reduction. Where applicable, spray drift assessments based upon this SDRT framework may then be based upon the van de Zande spray drift dataset (van de Zande and Holterman 2005). The drift model contains the appropriate regression values from van de Zande data to calculate the initial surface water PEC due to spray drift (PECsw) for buffer zones from 5 m to 20 m in 5 m intervals. The basis for this policy revision is detailed in a CRD regulatory update (CRD 2014). It is for this reason that the UK is represented in Figure 4.4 as operating two parallel drift representation schemes.

4.3.3 National options for mitigating spray drift

Typically, where spray drift mitigation is required to support safe use, product labels make reference to no spray zones. In a number of Member States, the maximum width of these no spray zones is constrained by national policy. Certain Member States also permit the use of drift reducing nozzles as an independent or complementary means of mitigating spray drift. Examples of other schemes are summarized in the